RANDOMIZED DOUBLE BLINDED CONTROLLED TRIAL TO COMPARE THE EFFICACY OF EXTENDED SPECTRUM ANTIBIOTICS VERSUS NARROW SPECTRUM ANTIBIOTIC AS PROPHYLAXIS IN CAESAREAN DELIVERY FOR THE PREVENTION OF POST CAESAREAN ENDOMETRITIS AND SSI"

DISSERTATION SUBMITTED IN THE PARTIAL FULFILMENT OF THE REQUIREMENTS OF TAMIL NADU DR.M.G.R. MEDICAL UNIVERSITY FOR THE DEGREE OF M.S. BRANCH VI (OBSTETRICS AND GYNAECOLOGY) EXAMINATION TO BE HELD IN APRIL 2016

CERTIFICATE

This is to certify that this dissertation entitled "**Randomized double blinded controlled trial to compare the efficacy of Extended spectrum antibiotics versus narrow spectrum antibiotic as prophylaxis in Caesarean delivery for the prevention of post Caesarean endometritis and SSI**" is a bonafied work done by Dr.Sivasankari in partial fulfilment of the requirement of the MS Branch (Obstetrics and Gynaecology) examination of the Tamil Nadu Dr.M.G.R Medical University, Chennai to be held in April 2016.

Signature of the Guide

Signature of the HOD

Signature of the Principal

DECLARATION CERTIFICATE

This is to certify that the dissertation titled "**Randomized double blinded controlled trial to compare the efficacy of Extended spectrum antibiotics versus narrow spectrum antibiotic as prophylaxis in Caesarean delivery for the prevention of post Caesarean endometritis and SSI**" which is submitted by me in partial fulfillment towards the M.S. Branch VI (Obstetrics and Gynaecology) Degree Examinations of The Tamil Nadu Dr.M.G.R. Medical University, Chennai to be held in April 2016 comprises only my original work and due acknowledgement has been made in text to all material used.

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Randomized double blinded controlled trial to compare the efficacy of extended spectrum antibiotics with narrow spectrum antibiotic as prophylaxis in Cesarean delivery for the prevention of post Cesarean endometritis.
Dr. Sivasankari, PG Registrar, Obstetrics - Unit 4, Dr. Ruby Jose, Dr. Manisha. M. Beck, Dr. Bhageerathy, Obstetrics and Gynaecology, CMC, Vellore.

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Dear Dr. Sivasankari,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

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Dear Dr. Sivasankari,

The Institutional Review Board (Silver, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Randomized double blinded controlled trial to compare the efficacy of extended spectrum antibiotics with narrow spectrum antibiotic as prophylaxis in Cesarean delivery for the prevention of post Cesarean endometritis." on November 26th 2014.

The Committee reviewed the following documents:

1. IRB Application Format
2. Curriculum Vitae' of Drs. Sivasankari, Ruby Jose, Manisha. M, Bhageerathy
3. Proforma
4. Permission Letter
5. GCP Certificate of Dr. Manisha. M. Beck
6. Informed Consent Form (English, Tamil & Telugu)
7. Information Sheet (English, Tamil & Telugu)
8. No of documents 1- 6

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Prof. Keith Gomez	BSc, MA (S.W), M. Phil (Psychiatry Social Work)	Student counselor, Loyola College, Chennai, Deputy Chairperson, Ethics Committee, IRB	External, Lay Person & Social Scientist
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Dr. P. Zachariah	MBBS, PhD	Retired Professor, Vellore	External, Clinician
Rev. Dr. T. Arul Dhas	M. Sc, BD, DPC, PhD(Edin)	Chaplaincy Department, CMC, CMC, Vellore	Internal, Social Scientist
Mr. C. Sampath	B. Sc, BL	Legal Expert, Vellore	External, Legal Expert
Mrs. Pattabiraman	B. Sc, DSSA	Social Worker, Vellore	External, Lay person
Mrs. Ruma Nayak	M Sc (Nursing)	Professor, Head of Paediatric Nursing & Deputy Nursing Superintendent, College of Nursing, CMC, Vellore	Internal, Nurse
Dr. Vinitha Ravindran	PhD (Nursing)	Professor & Addl. Deputy Dean, College of Nursing, CMC, Vellore	Internal, Nurse
Dr. Nihal Thomas	MD, MNAMS, DNB(Endo), FRACP (Endo), FRCP(Edin) FRCP (Glasg)	Professor & Head, Endocrinology. Additional Vice Principal (Research), Deputy Chairperson, IRB, Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

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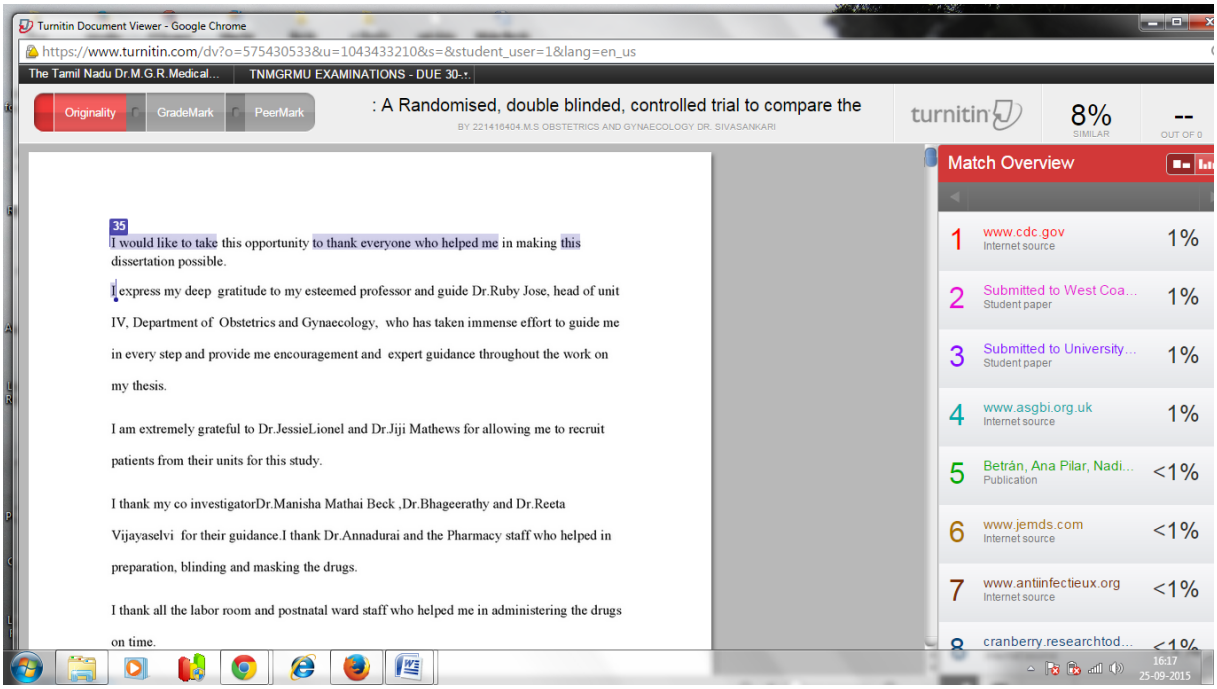
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I would like to take this opportunity to thank everyone who helped me in making this dissertation possible.
I express my deep gratitude to my esteemed professor and guide Dr.Ruby Jose, head of unit IV, Department of Obstetrics and Gynaecology, who has taken immense effort to guide me in every step and provide me encouragement and expert guidance throughout the work on my thesis.
I am extremely grateful to Dr.JessieLionel and Dr.Jiji Mathews for allowing me to recruit patients from their units for this study.
I thank my co investigatorDr.Manisha Mathai Beck ,Dr.Bhageerathy and Dr.Reeta Vijayaselvi for their guidance.I thank Dr.Annadurai and the Pharmacy staff who helped in preparation, blinding and masking the drugs.
I thank all the labor room and postnatal ward staff who helped me in administering the drugs on time.
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I would like to take this opportunity to thank everyone who helped me in making this dissertation possible.

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I am indebted to all the patients who consented to be part of this study.

A special thanks to family and friends ,especially my husband ,Dr.Karthik and my son Haricharan for supporting me throughout the work on this study.

Above all I thank God for His grace and mercy on me.

ABSTRACT

1. Title: A Randomised, double blinded, controlled trial to compare the efficacy of extended spectrum antibioticwith narrow spectrum antibioticas prophylaxis in Cesarian delivery in preventing post Cesarian endometritis and surgical site infections.

2. Department: Department of Obstetrics and Gynaecology, Christian Medical College, Vellore.

3. Degree and Subject: M.S, Obstetrics and Gynaecology

4. Word Count: 436

Background: Cesariandelivery(CD) is the most commonly performed surgical procedure worldwide. Infection related complications of CD are common and is potentially life threatening. Administration of prophylactic antibiotic prior to skin incision decreased the post CD infectious morbidity. Despite the prophylactic antibiotic there is a chance of 10-20% of postpartum infections due to different strains of micro-organisms and development of antibiotic resistant bacteria. To overcome this situation, adding the extended spectrum antibiotic along with standard antibiotic

would further decrease the incidence of endometritis, wound infection, and therefore ,length of hospital stay .There is need for more randomized controlled trials to compare the efficacy of preoperative administration of extended spectrum antibiotic with standard narrow spectrum antibiotic in preventing post CD infectious morbidity.

5. Objective: To compare the efficacy of a combination of antibiotics with standard care(intravenous Cefazolin and intravenous Azithromycin vs intravenous Cefazolin and intravenous placebo) administered as prophylaxis for CD in the prevention of infectious morbidity following Cesarian delivery.

6. Setting: Tertiary care Hospital in South India.

7. Methods: This was a randomised, double blinded, controlled trial, where mothers were randomised to the study protocol once they the decision was made for CD. Each of the randomised woman received two injections prior to skin incision (Inj. cefazolin along with study drug or Inj. Cefazolin with a placebo) according to the randomisation code. After CD, these women were monitored in the ward for evidence of infection or any adverse event the drug might have caused. They were followed up till 42 days post delivery for any infectious morbidity (surgical site infections, urinary tract infection and readmission).

8. Results: The total number of women recruited into the study were 635. Of these, 37 women had to be excluded due to following reasons. Three women who delivered vaginally after randomization, 3 women whose drug bottles was broken, and 1 women who was probably allergic to the study drug were excluded from the analysis. In addition, 25 women were lost to follow up and in 5, hospital numbers were not noted

and could not be entered into the study. The mean and SD for hospital stay for the mothers were 4.14 in the study group. Women who received extended spectrum antibiotic along with standard narrow spectrum antibiotic prior to skin incision had significantly less post CD endometritis, when compared with mothers who received standard narrow spectrum antibiotics alone ($p > 0.009$)

5. Conclusions: Extended spectrum antibiotic, when used as prophylaxis at CD resulted in significant reduction in postoperative endometritis whereas reduction in surgical site infections, UTI and hospital stay was not statistically significant when compared to narrow spectrum antibiotics.

AIMS AND OBJECTIVES

AIM:

To compare the efficacy of extended spectrum antibiotic with standard narrow spectrum antibiotic as prophylaxis at CD in the prevention of postCD endometritis and surgical site infection (SSI).

OBJECTIVES:

1.To compare the efficacy of extended spectrum antibiotics with narrow spectrum antibiotics on the following outcome ; endometritis, SSI, UTI, duration of hospital stay.

2.To compare the safety profile of extended spectrum antibiotics.

3.To compare the effect on other post operative complication like re admissions.

INTRODUCTION

Cesarian Delivery (CD) is the most frequently performed surgery in Obstetrics all over the world, to decrease the morbidity and mortality of both mother and neonate .The trend is seen to be consistently increasing throughout the world (1).According to the WHO global survey 2004-08, the overall CD rate increased overtime, from 26.4% to 31.2% in the moderate and low human development index (HDI) countries(2) .CD has more risk of postpartum complications like puerperal infection, endomyometritis, surgical site infection(SSI) ,urinary tract infections,(UTI),pelvic abcess, thromboembolic events, increased blood loss, and anaesthetic complications. Women with previous LSCS have an additional risk of intra abdominal adhesions ,bowel and bladder injuries, presence of placenta accreta and cesarian hysterectomy. These further increase maternal and neonatal morbidity and mortality, and increase the length of hospital stay,cost and pose further economical burden to the family(3). Endometritis is one of the frequently seen complications arising in about 15-20% of CD and the incidence is 5-85% (4). Most frequently, the microorganisms that are responsible for puerperal infections are polymicrobial, aerobic and anaerobic microorganisms. Ureaplasma urealyticum colonisation in the chorioamnion is most often seen in women with intact membrane and it is one of the independent predictors of subsequent endometritis (4).According to the CDC, SSI is defined as ,an infection occurring within 30days after a surgical procedure(without any implant) .Based on post discharge surveillance, the incidence was found to be 9.9% (5).In 2014, Cochrane review recommended that prophylactic antibiotics should be administered to all CDs to prevent infectious morbidity . It was found that there was 60-70% reduction

in the incidence of SSI, endometritis and serious infectious complications when compared with no antibiotic prophylaxis (6). The prophylactic antibiotic should have adequate tissue concentration, high safety, acceptable ecologically, easily administered and of low cost . According to the ACOG,SOGC, WHO, and NICE guidelines, the recommended prophylactic antibiotic is the first generation cephalosporin .The ACOG,SOGC, WHO,NICE and CDC guidelines , with level A evidence recommend , that prophylaxis should be administered 60 minutes before the start of CD .The guidelines state that, there were no significant neonatal risks or antibiotic resistance to other microorganisms on account of prophylactic antibiotics(7).

Despite the widespread use of prophylactic antibiotics, postpartum endometritis stays as an common complication following CD in about 10-20 % .The reasons behind this are ,that first generation cephalosporins do not cover Urea plasmaurealyticum , the most commonly seen microorganism causing endometritis, and narrow spectrum antibiotic alter the microorganism and increase resistant organisms like anaerobes. This paves the way , to add extended spectrum antibiotics like azithromycin, clindamycin, metronidazole or doxycycline (8).In many studies, azithromycin is proven to be effective due to its higher myometrial, adiposetissue, and placental concentration, low serum concentration, adequate coverage forureaplasma urealyticum and shown to be safely administered in pregnancy. In the present study we aim to compare the following outcome measures in the mother such as surgical site infection , endometritis , UTI ,length of hospital stay ,need for readmission, allergic reaction to study drug, and maternal death due to sepsis.

LITERATURE REVIEW

Cesarian Delivery (CD) is the most commonly performed surgical procedure in obstetrics worldwide. The introduction of CD was for the benefit of the mother and fetus , by decreasing their morbidity and mortality and thereby improving their outcomes(1). According to the UNICEF , it is the most important global indicator for measuring access to obstetric services (9).The CD rates are increasing rapidly and the current trend may result in even higher CD rates in the future(10)(11). There is a 50% rise in CD rates mostly due to an increase in the number of primary CD .Previous CD are an increasingly important determinant factor of overall increase in the rates of CD in countries with a medium or low Human Development Index (HDI).(2).

Trends of CD worldwide :

Ye et al, in 2015, analysed the rates of increase in CD from 2000-2012(12)

Year	World total	least developed	less developed	more developed
2000	12.0%(0.5-38.	2.0%(0.5-6.4)	13.1%(1.5-38.0)	19.5%(7.5-33.3)
2012	15.5%(1.4-55.	5.2%(1.4-17.9)	16.9%(1.7-55.6)	26.9%(13.9-38.1)
Relative Changes	1.3%	2.6%	1.3%	1.4%

In 2014, Kozhimannil et al ,conducted a retrospective multilevel analysis in the United States, to assess the incidence of CD and found that it was 33% overall , the incidence for primary CD being 22.0% (13).Vogel et al, in 2015,assessed the trend of

CD in 21 countries as a secondary analysis of two WHO multicountry survey. The rates of CD were as follows(2)

WHO SURVEY(2)

	Countries	Percentage for CD
Very high HDI countries	Argentina	35.1%
	Japan	19.8%
High HDI countries	Ecunda	40.3%
	Mexico	39.8%
	Peru	34.3%
	Sri Lanka	29.9%
	Brazil	27%
Moderate HDI countries	China	46.2%
	Paraguay	41.9%
	Thailand	34.1%
	Vietnam	35.9%
	Nicaragua	26.75%
	Philipines	17.9%
	India	17.7%
	Cambodia	14.7%
Low HDI countries	Kenya	16%
	Uganda	15%
	Nigeria	14.5%
Democratic republic of the congo	Nigeria	5.3%
	Nepal	20.4%

The WHO survey estimates the annual expected rise in CD in developing countries to be 10-15%(14).In 47.2% of the countries around the world, the CD rate increased by 15% . Latin America , the Caribbean along with Europe, North America and Oceania had the highest values(15,16).The overall CD rate increased overtime from 26.4% to 31.2% according to a WHO global survey done in 2004-08. A population based study was done in Germany, concluded that ,CD in those with secondary CDs show a rising trend ,from 17.2% in 1990 to 35.2% in the year 2012 ($p<0.01$)(17).

Trends of CD in India :

In the WHO's Global Survey done by Vogel et al in 2015,the CD rate, which is an important criteria of the HDI, was found to be 17.7% in India(2).According to the National Family Health Survey2010, the incidence of CD in India was facing rising trends as well.(18). The highest CD rate in India was found to be 17.9 % ,the highest were found urban population in Kerala, Goa, Andhra Pradesh and West Bengal are30% and 17.8% (19).

Rates of CD in India(19)

State	Rural	Urban
Andra Pradesh	19.4%	32.25
Assam	3.7%	17.4%
Bihar	2.5%	7.6%
Delhi	5.0%	12.6%
Goa	23.7%	27.3%

Gujarat	5.5%	14.7%
Haryana	3.1%	12.1%
Himachal Pradesh	12.3%	15.4%
Jammu and Kashmir	9.2%	29%
Karnataka	11.6%	22.2%
Madhya Pradesh	1.9%	13.6%
Maharastra	7.7%	19.9%
Orrisa	3.9%	12.8%
Punjab	14.8%	19.6%
Kerala	28.4%	33.5%
Rajesthan	2.2%	9.9%
Tamil nadu	19.8%	26%
Uttar Pradesh	2.4%	12.7%
West Bengal	5.8%	30.1%
India	6.2%	17.8%

In the Christian Medical College and Hospital (CMCH), there were 14,276 deliveries in the year 2014.The total number of CDs were 3985 and the CD rate was 29%.

The indications for CD were the following: non-reassuring fetal status (32%), labour arrest disorders (18%),multiple gestation (16%) suspected macrosomia (10%),pre-eclampsia (10%),CD on maternal request (8%), maternal-fetal conditions (5%), other obstetric conditions(1%) and previous LSCS(20).

Although there is an increasing trend in CDs, the reasons vary from social to medical , financial, cultural changes, and medicolegal considerations (21)(22).CD has become a safe procedure because of advances in Anaesthesia and, surgical skills and material, and therefore women opt for this electively. In addition, of late ,there has been a rise in high risk pregnancies in the elderly, obese, infertility treated women(23). The prevalence of pre-gestational and gestational diabetes which were significant risk factors for a primary CD, have been increasing steadily (24).

Some other factors that promote CD is prior CD, very low birth weight of babies, multiple pregnancy, policy of elective CD for breech presentation and increasing maternal BMI(25).Extremes of neonatal birth weights were also associated with increased risk of CD(26).

Complications of Cesarian delivery:

Maternal :

Immediate complications:

1.Anaesthetic complication 10.5% ,the most common was haemodynamic fluctuations(27)

2.Primary PPH (3-15%)(28)

3. Haematoma and reoperation seen more in LBW and gestational age less than 30 weeks, blood loss >1000mL and need for blood transfusion (29) .

4. Lowerurinary tract (LUT)injury remained relatively uncommon (0.3 %)(30)

Remote complications:

1. Postoperative pain

2 .Postpartuminfection(endometritis,UTI,wound infection) (3)

3. Thromboembolism(1 per 10,000) in the first week after CD(31)

Complication after previous LSCS:

1. Dense adhesion ,more significant after 4 CD(P>0.05)(32)

2. Increased length of hospital stay

3. Increased risk of bowel and bladder injury

4. Placentaprevia and placenta accrete

5. Increased need for blood transfusion

6. Serious maternal morbidity is highly increased when the number of CD increase.(33)

Fetal complications of CD:

Planned CD is associated with increased neonatal respiratory complications(34).The prevalence of neonatal complications is more in CD prior to the onset of labour .These are mainly respiratory problems, which occur when do neat early term gestation(35).An Australian study in 2014,on neonatal outcome after elective CD showed that early term CD was associated with significant increase in fetal morbidity like admission to Neonatal critical care unit (NCCU) due to severe respiratory morbidity needing assisted ventilation mechanically or by continuous positive airway pressure(CPAP), transient tachypnoea of newborn(TTN) ,respiratory distress syndrome (RDS), primary pulmonary hypertension(PPHN) ,depressed at birth, low apgar score ,admission in NNCU 1-5 days, jaundice needing phototherapy, hypoglycaemia ,SGA and LGA(36) .

Reasons for wanting to reduce the CD rate:

CD on maternal request is a term adopted and endorsed by a 2006 National Institutes of Health (NIH) state-of-the-science conference that women have a right to request for elective CD, but the risks associated with this should be analysed. In 2013 , O'Neill et al , in a systematic review of 11 articles ,found that there were associated risks .CD may increase the risk of stillbirth by 23%insubsequent pregnancy when compared with previous vaginal delivery (37).Repeat CD has increased rates of intra-operative complications, placental abnormalities such as placenta previa and accreta, and consequent gravid hysterectomy, iatrogenic prematurity of the baby , repeated CDs and difficulties during surgery, increased morbidity and mortality of the mother and

fetus, organ injury ,pain, anaesthetic complications, infections, cost, length of hospital stay, use of resources(38).

Strategies to reduce CD rates:

Robson ten group classification of LSCS:

In order to propose and implement effective measures to reduce CD rates an appropriate classification of CD is required. In 2011, a systematic review concluded that the Robson classification or 10-group classification would be the best and internationally applicable classification for the same(39)(40).

1. Nulliparous, singleton, cephalic, ≥37 weeks gestation, in spontaneous labour
2. Nulliparous, singleton, cephalic,≥37 weeks gestation, induced or CD before labour

   2a Nulliparous, singleton, cephalic,≥37 weeks gestation induced labour

   2b Nulliparous ,singleton,cephalic, ≥37 weeks gestation labour CD before labour.

3. Multiparous (excluding previous CD,singleton,cephalic pregnancy, ≥37 weeks gestation in spontaneous labour
4. Multiparous without a previous uterine scar,with singleton,cephalic pregnancy ≥37 weeks gestation, ,induced or CD before labour

4a. Multiparous without a previous uterine scar, with singleton, cephalic Pregnancy≥37 weeks gestation, ,induced labour

4b. Multiparous without a previous uterine scar, with singleton, cephalic Pregnancy≥37 weeks gestation, CD before labour

5. Previous CD, singleton, cephalic ≥37weeks gestation.

6. All nulliparous with a single breech

7. All multiparous with a single breech(including previous CD)

8. All multiple pregnancies(including previous CD)

9. All women with a single pregnancy in transverse or oblique lie (including those with previous CD)

10. Allsingleton, cephalic,<37 weeks gestation pregnancies((including previous CD)

Increase in CD rates are multifactorial in aetiology and can be safely decreased by complex intervention. The evaluation and identification of maternal risk factors, re-evaluation and analysis of the indications for induction of labour , counselling for trial of labor after CD (TOLAC) after detailed evaluation of previous CD, and external cephalic version for non complicated breech presentation are most important ways to lower the CD rates.(41)The meta analysis done by Nils chailet et al ,revealed evidence based strategies for reducing the rates of CD .The safest way to reduce CD rates were upto the health care workers who should analyze and modify

their practice .Audit and feedback is an effective strategy, to improve the clinical practice, quality improvement and can, thereby reduce CS by 13% when used alone and when used along with multifaceted strategy , can be reduced to 27%. Multifaceted strategies were effective and strong in reducing CD rates.(42)Lotfi et al ,concluded that the strategies that could work to reduce the CD are : allowing qualified midwives to conducting normal vaginal deliveries, skilled obstetricians in management of complicated deliveries, counselling the community about the complications of CD and its outcome, educating patients regarding the chance of repeat CD ,by helping the mothers to understand and make a proper decision regarding their delivery and by promoting standards and developing regulations and legislations to provide good quality care.(43)

Puerperal Infections:

Puerperal sepsis is a leading cause of maternal mortality in the world .(44)Endometritis (endomyometritis or endomyoparametritis), wound infection, mastitis, urinary tract infection, and septic thrombophlebitis are the major causes for puerperal infections and most of them occured after hospital discharge.(44)Septicemia, endotoxic shock, peritonitis or abscess formation are other serious maternal complications .There is a chance of increased infection in post partum women by 15-24% and is a leading cause for preventable maternal mortalitily rate .There is an 5- to 20fold estimated increase in incidence of CD in the future and CD is the single most important risk factor for puerperal infection.(45)

Predisposing factors (46)**:**

1. Home birth in unhygienic conditions

2. Low socioeconomic status

3. Poor nutrition

4. Primiparity, anemia

5. Prolonged rupture of membranes

6. Prolonged labour

7. Multiple vaginal examinations in labour

8. Cesarian Delivery

9. Obstetrical maneuvers

10. Retained products within the uterus

11. Postpartum hemorrhage.

12. Young maternal age

14. Presence of Ureaplasma in the genital tract

Causative micro-organism :

The causative organisms are polymicrobial in nature. Aerobic and anaerobic infections were found in 48.1% patients who delivered vaginally and in 58.4% delivered by CD. The most common aerobic organisms were Staphylococcus epidermidis, E. coli, Enterococococci and Streptococci and , the most common anaerobic organisms were the grampositive anaerobic cocci, Peptostreptococcus and Peptococcus, and Bacteroides species. When the prophylactic antibiotics were not given for CD,G vaginalis (39%)and anaerobes(45%) were the most common microorganism associated with endometritis(47). Gestner et al found that anaerobic microorganism played an important role in the pathology of post partum endometritis and that it was caused frequently by a polymicrobial aerobic and anaerobic micro organism(25) Aerobic gram-negative infection of 7%-25% is seen in cultures done for postpartum infections.(48)Awadalla et al found that there was 16.8% of aerobic and anaerobic micro organisms found in endometrial cultures from those who developed endomyometritis. He stated that there was a statistically significant relationship between positive cultures and the development of endomyometritis.(49)

a.**Endometritis:**

Endometritis is one of the most common complications which causes febrile morbidity after CD with an incidence of about 5%-85%.(50). Endometritis increased post CD hospital stay by 3 days and hospital cost by $850 in a study done by donowitz et al(51) . It is five times more commonly seen following CD than vaginal delivery , which comprises15% to 20% of women delivered by CD (51). Postpartum

endometritisis caused when the vaginal organisms ascend to the endometrial cavity during labor and cause infection. (52) . Postpartum endometritis is the infection confined to the decidua - endometrium. This infection can extend into the myometrium and is then called endomyometritis and if it involved the parametrium then it is called as parametritis(53). At CD, highly virulent bacteria and Mycoplasma hominis predict the development of postpartum endometritis and during vaginal delivery, aerobic gram negative rods and bacterial vaginosis were the culprits.(54) . Despite the widespread use of prophylactic antibiotics, postpartum endometritis remains a common complication following CD. Chaim et al found that severe PIH , fetal distress, perinatal mortality, Apgar score less than 3 and 7 after 1 and 5 minutes were the variable factors associated with postpartum endometritis.(55) Colonization of the chorioamnion with Ureaplasma urealyticum in women with intact membranes being delivered by Cesarian was a significant, independent predictor of subsequent endometritis(4).

Postpartum endometritis is defined as having a temperature of 100.4 F or more, associated with uterine tenderness , foul smelling or purulent lochia and leucocytosis more than 12,000 per mm3 without other pelvic infections.

Prophylactic antibiotics at CD are highly effective in reducing postCesarian endometritis (56).According to the CDC/(NHSN)National Health care Safety Network surveillence, the definitions for specific type of infections(Endometritis(EMET))must meet at least one of the following criteria:(57)

1. Patient has organism cultured from endometrial fluid or tissue(including amniotic fluid)

2. Patient has at least two of the following symptoms fever(>38.0C +/-),pain or tenderness(uterine or abdominal), or purulent drainage from uterus.

Despite prophylactic antibiotics, endometritis occurs in 10–20% of women after CD, which further increases the morbidity. This could be due to the development of antibiotic resistance in the microflora of the upper genital tract and abdominal wound (10) A combination of Clindamycin and Gentamicin is appropriate to treat postpartum endometritis.(52)

b)Wound infections/ SSIs :

NHSN data showed an overall SSI rate of 1.9% (2006-2008)(58).SSI were the most common health associated infections, accounting for 31% of all HAIs among hospitalized patients (59).Surgical site infection is one of the type of health care associated infection that occurs after an invasive procedure .According to NICE guidelines, SSI accounts for upto 20% of HAI s; 5% of patients who had surgery have SSI .(60)An SSI may occur spontaneously as wound discharge after 7-10 days from the time of surgery or as life threatening complications. Most SSI s are caused by the micro organism from the patient's own body. Less SSI occur due to exogenous microorganisms. Most of the SSI s are preventable by measures taken during pre, intra and post operative care.(60)Surgical site infection is defined, according to the US Centers for Disease Control and Preventions (CDC), as an infection occurring within 30 days after a surgical procedure (without any implant) .SSI is a significant cause of

post-surgical morbidity and mortality which leads to increase in the length of the hospital stay , cost, and causing a huge socioeconomic burden to the family .

SSIs were classified as superficial or deep. A superficial wound infection was defined as infection of the skin and superficial tissues at the incision. Deep space infection was defined as infection involving the deep tissues such as the fascia and muscle layers(61).According to CDC guidelines CD without evidence of chorioamnionitis, would be classified as a clean contaminated surgical wound and if it was associated with chorioamnionitis, irrespective of the duration of rupture of membranes, it would be classified as dirty or infected surgical wound (62). A prospective cohort study done by Opoien et al found the incidence of SSI to be 8.9%, when a 30 day post-operative follow up was done , when compared to 1.8% noted at the time of hospital discharge(63).The incidence of SSI was higher following elective CD according to postdischarge surveillance was 9.9%(5) .

Risk factors for development of SSI

1. Operating time > or = 38min
2. BMI>30kg/m2
3. Development of subcutaneous hematoma after the procedure for skin closure(64)
4. Absence of antibiotic prophylaxis, duration of rupture of membrane(65)
5. Internal fetal monitoring ,chorioamnionitis(66)
6. African-American race(67)

7. Number of vaginal examinations before surgery, duration of operation, vertical skin incision and category of surgeon (68)
8. Anderson et al found that there was a strong relationship between obesity and surgical site infection (SSI) in women undergoing elective CD(69) and emergency CD.
9. Twin delivery, hypertensives ,diabetes complicating pregnancy(pre gestational and gestational), (70).

CDC Criteria for defining surgical site infection (SSI):(63)

Superficial incisional SSI:

Infection occur within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision and at least one of the following

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.

2. Organism isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.

3. At least one of the following signs or symptoms of infection : Pain or tenderness, localized swelling, redness, or heat and superficial incision deliberately opened by surgeon, unless incision is culture – negative.

4.Diagnosis of superficial incisional surgical site infection(SSI) by surgeon or attending physician

There are two specific types of superficial incisional SSIs:(71)

1.*Superficial Incisional primary(SIP)*- a superficial incisional SSI that is identified in the primary incision in a patient that has had an operation with one or more incision (e.g., CD incision, chest incision for coronary artery bypass graft(CBGB)

2. *Superficial Incisional secondary (SIS*)- a superficial incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (e.g., donar site incision for CBGB)

Deep incisional SSI

Infection occurs within 30 days after the operation and infection involves deep soft tissue (eg. fascial and muscle layers) of the incision and at least one of the following

1.Purulent drainage from the deep incisional but not from the organ/space component of the surgical site.

2.A deep incisional spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever(>38C),localized pain, or tenderness, unless site is culture-negative.

3.An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation,or by histopathologic or radiologic examination.

4.Diagnosis of a deep incisional SSI by a surgeon or attending physician

There are two specific types of superficial incisional SSIs:

1. Deep Incisional primary(DIP)- a deep incisional SSI that is identified in the primary incision in a patient that has had an operation with one or more incision (e.g., CD incision, chest incision for CBGB)

2. *Deep Incisional secondary (DIS)*- a deep incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (e.g., donar site incision for CBGB)

Organ/Space SSI:

Infection occurs within 30 days after the operation and infection involves any part of the anatomy (e.g. organ or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following:

1. Purulent drainage from a drain that is placed through a stab wound into the organ/space.

2. Organism isolated from an aseptically obtained culture of fluid or tissue in the organ/space.

3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

4. Diagnosis of an organ/space SSI by a surgeon or attending physician.

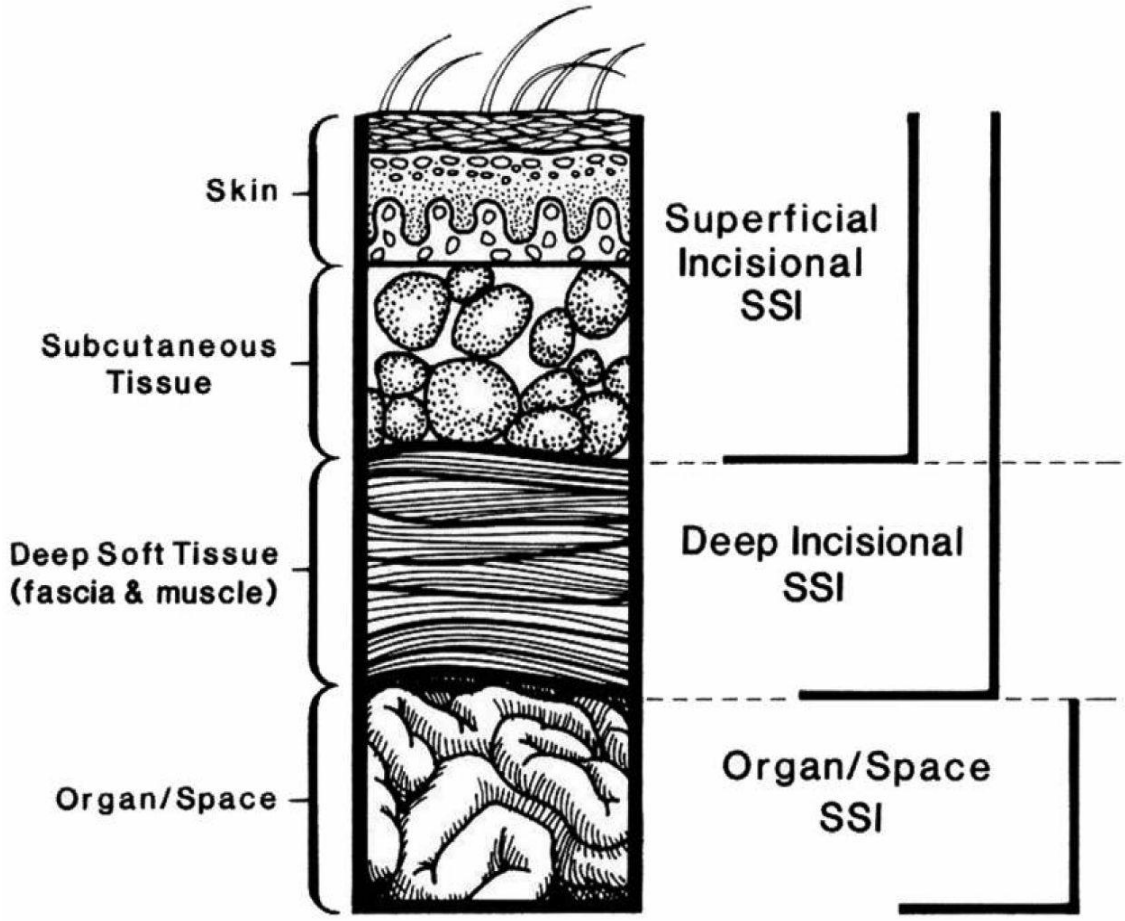
Do not report the following condition as SSI:

1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).

2. Infection of an episiotomy or newborn circumcision site.

3. Infected burn wound.

4. Incisional SSI that extends into the fascial and muscle layers.



Centers for Disease Control and Prevention's National Healthcare Safety Network classification for surgical site infection (SSI).

MICROBIOLOGY

Microorganism most commonly associated with wound infections are ureaplasma urealyticum, coagulase negative staphylococci and enterococcus faecalis. Roberts et al found that wound infections develop due to contamination from the lower genital tract during surgery and had a higher prevalence of enterococcus faecalis(72). Genital mycoplasmas are the most prevalent bacterium in post Cesarian wound infection.(73) Staphylococcus aureus, coagulase-negative staphylococci, Enterococcus spp, and Escherichia coli are the most commonly identified microorganisms in surgical site infection. Methicillin-resistant staphylococcus aureus(MRSA),an antimicrobial-resistant pathogen seen in increasing proportion of SSIs, is the most common pathogen seen in superficial incisional and complex SSI s(74)

PATHOGENESIS:

The important precursor of SSI is microbial contamination of the surgical site.

The dose of bacterial contamination 3 microorganism virulence = Risk of surgical site infection

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Resistance of the host patient

The risk of SSI is increased markedly when the surgical site is contaminated with >105 5microorganism per gram of tissue, then there is a chance of increased risk of

SSI(75). The role of cytokine is pivotal in both immunity and inflammation. Cytokine plays a complex role between host and exogenous microorganism(76). When the incision is made near the perineum or groin the chance of contamination with fecal flora is more.

Risks factors that can increase the development of surgical site infections(77):

Patient Characteristics

1.Age

2.Nutritional status

3.Diabetes

4.Smoking

5.Obesity

6.Coexistent infections at a remote body site

7.Colonization with microorganism

8.Altered immune response

9.Length of perioperative hospital stay

Operative Characteristics

1. Duration of surgical scrub

2. Skin antisepsis

3. Preoperative shaving

4. Preoperative skin preparation

5. Duration of operation

6. Antimicrobial prophylaxis

7. Operating room ventilation

8. Inadequate sterilisation of instruments

9. Foreign material in the surgical site

10. Surgical drain

11. Surgical technique

a. Poor haemostasis

b. Failure to obliterate dead space

c. Tissue trauma

Recommendation for prevention of surgical site infection (78)**:**

1. Preoperative :

a. Preparation

1. Identify and treat all infection before elective surgery.

2. Avoid preoperative hair removal.

3. If hair removal needs to be done, use electric clippers

4. Avoid preoperative hyperglycemia and adequate control of blood sugars.

5. Instruct patient to avoid or abstain peri operatively from smoking cigarettes, cigars, or other form of tobacco.

6. Blood products to be given if indicated.

7. Instruct patient to take a bath or shower before surgery.

8. Complete wash and clean at and around the incision site.

9. Use an appropriate antiseptic agent for skin preparation.

10. Skin painting start as a concentric circle and move towards periphery

11. Shorter perioperative hospital stay.

12. Do not stop or taper the steroids preoperative, if the patient is on steroids.

13. Nutritional support to prevent SSI.

14. Preoperative mupirocin is not recommended for the prevention of SSI

15. Wound space oxygen is not recommended to prevent SSI.

b. Surgical team members hand/forearm antisepsis:

1. Short nail .

2. Two to five minutes of hand and forearm upto elbow scrub with appropriate antiseptic solution

3. Dry hands, sterile gown and gloves

4. Remove hand or arm jewellery

Infected and colonized surgical personnel management:

1. The surgical personnel has to be educated and encouraged to inform their supervisory staff, when they have signs and symptoms of a transmissible infectious illness.

2. To develop well defined policies concerning patient care responsibilities when the surgical personnel have transmissible infections.

3. When the surgical personnel has any signs and symptoms of transmissible infections obtain culture and exclude them from duty and adequately treat them.

Antimicrobial prophylaxis:

1.Antimicrobial prophylaxis to be administered according to guidelines and has to be administered within 1 hr before the skin incision to attain maximum tissue concentration (79)

2. Choose an antibiotic which is effective for the most common pathogen causing SSI for that particular procedure.

3. Discontinue antibiotic within 24hrs after surgery.

4.Dose of the antibiotics to be adjusted according to patient weight – 2gm Inj. cefazolin for patient weighing > 80kg and 3gms for > 120kg.(7)

5. Prophylactic antibiotic should be re-administered for a prolonged surgery and increased blood loss.(7)

Intraoperative:

a.Ventilation:

1a.For Positive pressure ventilation, guidelines of the American institute of architect – parameters for operating room ventilation(1996),need to be followed.

Temperature – 68-73 F, depending on normal ambient temperatures

Relative humidity - 30%-60%

Air movement – from clean to less clean areas

Air changes – Minimum 15 total air changes per hour and minimum 3 air changes of outdoor air per hour.

b. Cleaning and disinfection of environmental surfaces

1. Clean the affected area with EPA- approved hospital disinfectant before next surgery when there is visible soiling or contamination with blood or other body fluids.

Surgical attire and drapes:

1. When entering the operating room wear a mask which fully covers the mouth and nose.

2. Cap has to cover the entire hair on the head.

3. Sterile gown and glove to be worn by all members of the surgical team.

Asepsis and surgical technique:

1. Asepsis to be maintained with intravascular devices like central venous catheters, spinal or epidural anaesthesia catheters and while administering intravenous drugs.

2. Gentle tissue handling and complete haemostasis and obliteration of dead space.

3. Drain has to be kept through a separate incision away from the operation site if required.

Postoperative incision wound care:

1. Sterile dressing has to be in place for 24-48hrs.

2. Before and after dressing or any contact with operation site ,wash hands.

3. Asepsis to be maintained while changing dressing.

4. Patient and family members to be educated regarding wound care and the signs and symptoms of surgical site infections and to be reported if any occurs.

Methods for surveillance of SSI(80):

1. The direct method

2. The Indirect method

3. Automated data system

The direct method for surveillance of SSI:

a. The most accurate method for SSI surveillance is the direct method , in which the postoperative surgical site will be inspected daily from 24 to 48 hours by the physician , physician extender , registered nurse , or infection prevention and control professional (81).

b. The direct method is not practically easy and it is not used routinely due to its utilization of resource.

c. The direct method is the gold standard for research.

The Indirect method for surveillance for SSI:

a. Retrospective analysis of patient medical records and microbiology report .

b. Information from patient and surgeon

c. Evaluation of readmission to ward and operating room

d. Review of other information like coded diagnosis, coded procedures, operative reports, and antimicrobial prescriptions.

3. The indirect method for surveillance of SSI can be done by infection prevention control professionals and is less time consuming..

4.The indirect method for surveillance for SSI is specific and reliable and the sensitivity is 84% to 89% and specificity is 99.8% when compared with the gold standard of direct surveillance of SSI.(82)

5. The superficial incisional infections occurs post discharge, the indirect method for surveillance of SSI is not reliable and it cannot be used. (74)

Automated data system:

This can be used to expand the surveillance of SSI and by using hospital databases i.e; procedure and diagnosis code, use of antimicrobial and number of days administered, readmission to the hospital and operating room, surgical procedure data and demographic information into single database system. Computer assisted ,laboratory – based and case confirmation by surgeons need less time and are more efficient than conventional method and permits with reliable accuracy for SSIs surveillance(83)

Post discharge surveillance:

Post discharge surveillance (PDS) for surgical site infections last from 30 days for implant free procedures like CD and it can be maximum of upto 90 days for implant surgeries(84). Most SSI develop after hospital discharge(85) and it has been under estimated due to decline in the length of hospital stay ,more ambulatory service for surgical procedures and no post discharge surveillance. Mannien et al found a feasible and sensitive method of follow up to be post discharge follow up to the hospital and it

might be used internationally(86).PDS is important for estimation of incidence of post-CD SSI . Meire Celeste et al says that 15-days of post discharge follow-up for post Cesarian SSI is needed and it is appropriate to estimate the accurate rate of post Cesarian SSI and it was shown to be sufficient(87).The proportion of SSIs found through the PDS can be different due to the method of PDS used, the operative procedure, the type of SSI and the settings. Barwolff et al used the Krankenhaus Infektions Surveillance System (KISS) for collecting data on surgical site infections (SSIs) following CD and this study showed that continuous surveillance and comparison with stratified reference data can be used to reduce SSI infection rates after CD(88). Follow-up was not possible for all the patients, and so the incidence of post Cesarian SSI s was underestimated. With the use of PDS the incidence of SSI s following elective CD was higher than the expected(5).The Scottish national data recommend a procedure-specific approach to PDS, with direct observation of patients after CD, where the length of hospital stay is short, and showed that for CD the rate of SSI when PDS was performed was significantly higher than that when PDS was not performed ,with significant p value P<.01 (89).A good method is important than the duration of post discharge surveillance for surgical site infections.

Antibiotic Prophylaxis in Cesarian Delivery:

CD has an increased risk of infectious morbidity when compared to vaginal delivery. The CD rate is on a steady upward trend, and as CD rates increase, so does the infectious morbidity. One needs to think about the most effective antibiotic to reduce this morbidity .In the 2014 Cochrane review, comparison was made using antibiotic versus placebo for the prevention of infection following CD .There were 95 studies

that were studied , in which 15,000 women participated. They were analysed in terms of maternal febrile morbidity, wound infection, endometritis , serious infectious complications, urinary tract infections, hospital stay , adverse effects .The review recommended that prophylactic antibiotics should be administered to all women having CD to prevent infectious morbidity .It was found that there was 60-70% reduction in the incidence of wound infection, endometritis and serious infectious complications when compared with no antibiotic prophylaxis (78). Despite using prophylactic antibiotics, 10-20 % women develop endometritis after CD which further increases the morbidity, hospital stay and economic burden to the family. The reason for this could be attributed to microfloral antibiotic resistance and changes in the microflora of the endometrium(29).It is important to use the most effective antibiotic with the least adverse effect .The choice of antibiotics should be based on factors such as cost, half life safety, antimicrobial resistance and spectrum of activity. The principles for prevention of surgical site (SSI)infection are skin asepsis, surgical technique and antibiotic prophylaxis(79). Prophylactic antibiotics decrease the amount of bacterial contamination at the time of surgery and at the surgical site and maintain adequate antibiotic level in the tissue at the time of surgery.

Classification of antibiotics:

A.Penicillins:

Penicillins consist of a thiazolidine ring connected to a B-lactam ring to which is attached a side chain. The penicillin nucleus itself is the chief structural requirement

for biological activity. Penicillins are the oldest class of antibiotics and function by inhibiting cell wall

synthesis (bactericidal)

A1. Natural penicillins are based on the original penicillin-G structure. Examples include:

penicillin G; procaine, penicillin V; benzathine

A2. Penicillinase-resistant penicillins are active even in the presence of the bacterial enzyme that inactivates most natural penicillins. Examples include: cloxacillin; dicloxacillin; methicillin; nafcillin; oxacillin

A3. Extended spectrum penicillins which are effective against a wider range of bacteria.

Examples include: ticarcillin; piperacillin; carbenicillin; timentin

A4. Aminopenicillins also have an extended spectrum of action compared with the natural penicillins. Examples include: ampicillin; amoxicillin

A+. Penicillin combinations. Examples include: co-amoxyclav = 'ampicillin+ clavulanic acid' (Trade names include: Augmentin; Clavamox; Tyclav); 'ampicillin + sulbactam' (Trade names include: Ampictam; Unasyn)

B. Cephalosporins: Cephalosporins have a similar basic structure to penicillins but with different side chains.They function by inhibiting cell wall synthesis

B1. First generation cephalosporins; examples include: cephalothin; cefazolin; cephapirin; cephradine; cephalexin; cefadroxil

B2. Second generation cephalosporins; examples include: cefoxitin; cefaclor; cefuroxime; cefotetan; cefprozil; cefamandole, cefonicid; ceforanide, cefotiam

B3. Third generation cephalosporins, examples include: cefotaxime; ceftizoxime; ceftriaxon; cefpodoxime; cefditoren; ceftibuten; ceftazidine; cefcapene; cefdaloxime; cefetamet; cefixime; cefmenoxime; cefodizime; cefoperazone; cefpimizole

B4. Fourth generation cephalosporins, examples include: cefepime; cefpirome; cefclidine; cefluprenam; cefozopran; cefquinome

B+: Cephalosporin combinations. Examples include: 'cephradine + metronidazole'; 'ceftriaxone+ metronidazole'; 'cloxacillin + gentamicin'

C. Fluoroquinolones: The fluoroquinolones target the bacterial DNA gyrase and topoisomerase. They are potentbacteriocidal agents against a broad variety of micro-organisms**.**

Examples : ciprofloxacin; levofloxacin; lomefloxacin; norfloxacin; sparfloxacin; clinafloxacin; gatifloxacin; ofloxacin; trovafloxacin.

D. Tetracyclines : Tetracyclines are bacteriostatic antibiotics active against a wide range of aerobes and anaerobic gram-positive and gram-negative bacteria. They inhibit bacterial protein synthesis by binding to the 30S bacterial ribosome

Examples include: tetracycline; doxycycline; minocycline.

Chloramphenicol is considered to have similar action to tetracycline

E. Macrolides Macrolide antibiotics inhibit bacterial protein synthesis. Resistance can arise

Examples include: erythromycin; clarithromycin; azithromycin

F. Other beta-lactams (carbapenems) Carbapenems are beta-lactams that have a broader spectrum of activity than most other beta-lactam antibiotics

Examples include: imipenem; meropenem; ertapenem; aztreonam, mezlocillin

G. Aminoglycosides Aminoglycosides are first-line therapy for a limited number of very specific, often historically prominent infections, such as plague, turaremia and tuberculosis

Examples include: streptomycin; gentamicin, kanamycin.

H. Lincosamides Lincosamides are protein synthesis inhibitors which bind to the 50s subunit of bacterial ribosomes and inhibit early elongation of peptide chain by inhibiting transpeptidase reaction

Examples include: lincomycin; clindamycin.

I. Nitroimidazoles Nitroimidazole is an imidazole derivative that contains a nitro group. It is used for the treatment of infection with anaerobic organisms

Examples include: metronidazole, tinidazol

The most commonly used types of antibiotics are penicillins, cephalosporins, fluoroquinolones, tetracyclines and macrolides. There are four groups of penicillin and four generations of cephalosporin, the newer cephalosporin generation has a extended spectrum of activity and they both have common chemical structure , bactericidal activity, acting through inhibiting cell wall synthesis. Fluroquinalones are the newer group of antibiotics, they are synthetic, and the newer class has broad sprectrum activity and act by interferinge with the ability of bacteria to make DNA. Tetracyclines and Macrolides are derived from streptomyces bacteria and are broad-spectrum bacteriostatic antibiotics and are also bacteriostatic in action, binding to bacterial ribosomes. Aminoglycosides are used to treat gram-negative bacteria . The major adverse effects of antibiotics need to be considered. It can be associated with GI symptoms like nausea, vomiting, diarrhoea, skin rashes and joint pain and rarely anaphylactic reaction .Wide use of antibiotics can cause the development of drug resistant strains of bacteria (80).Roberts et al found that there is a difference in ampicillin and cefazolin prophylaxis on endocervical and endometrial microorganism for postpartum infections, ampicillin for aerobic gram negative rods and cefazolin for enterococcus and anaerobes. But there was difference in endometritis cure rates even though they had similar therapeutic action (59).

Cochrane Review 2014 on Comparison of different classes of prophylactic antibiotics for the prevention of post CD infectious morbidity (90)

Study	Antibiotic regimen	Outcome			Result
13 studies, 4010 women	Single cephalosporin vs single penicillin	Endometritis	SSI	UTI	No significant difference between two groups of antibiotics
		RR 1.11 CI -0.81 to 1.52	RR0.83 CI-0.38 to1.81	RR1.48 CI-0.89 to 2.48	
12 studies , 2875 women	Single cephalosporin vs penicillin combination	RR 0.90 CI – 0.60 to 1.35	RR 0.72 CI-0.40 to1.30	RR 0.66 CI-0.17 to 2.55	No significant difference between two groups of antibiotics
One study, 147 women	Cephalosporin combination vs single penicillin	RR 2.70 CI-0.65 to 11.55	RR 2.02 CI-0.42 to 9.63	-	No significant difference between two groups of antibiotics
Two studies women	Cephalosporin combination vs penicillin combinatic	RR 0.33 CI – 0.01 to 0.77	RR1.23 CI – 0.42 to 3.58	-	No significant difference between two groups of antibiotics
Two studies, 822 women	First generation cephalosporin (cefazolin, cephazoline, Cephadrine + metronidazole) vs extended spectrum penicillin(pipercillin)	RR 2.18 CI – 1.30 to 3.66	RR 2.02 CI-0.92 to 9.62	-	Higher incidence endometritis in first generation cephalosporins but no difference in SSI
Eight studies 1882 women	First generation cephalosporin vs aminopenicillin	RR 1.09 CI 0.69 to 1.71	RR 0.85 CI 0.36 to 2.01	RR 1.41 CI 0.54 to 3.70	No significant difference between two groups of antibiotics

Six studies , 2077 women	Second generation cephalosporin vs extended spectrum penicillin	RR 1.10 CI-0.78 to 1.54	RR 2.37 CI -0.64 to 8.73	RR1.43 CI-0.67 to 3.07	No significant difference between two groups of antibiotics
Two studies ,359 women	Third generation cephalosporin (ceftizoxime, ceftriaxone) vs extended spectrum penicillin (piperacillin , mezlocillin)	RR 2.14 CI- 1.14 to 4.00		-	Endometritis is more in cephalosporin group
Eight studies ,1921 women	Second generation cephalosporin (cefotetan, cefamandole, cefonicid, cefoxitin, cefuroxime) vs aminopenicillin (ampicillin, ampicillin / sulbactum, amoxicilli clavulanic acid)	RR 1.01 CI-0.75 to 1.35	RR 1.14 CI-0.47 to 2.78	RR0.63 CI- 0.11 to 3.66	No significant difference between two groups of antibiotics
Seven studie 1904 women	Third generation cephalosporin (ceftriaxone, ceftizoxime, cefotaxime, cefoperozone) vs aminopenicillin (ampicillin/ cloxacillin, amoxicillin /clavulani acid,ampicillin)	RR-1.47 CI- 0.89 to 2.42	RR-0.49 CI-0.27 to 0.90	RR-0.52 CI-0.10 to 2.80	SSI – significant reduction in cephalosporin group
One study , 72 women	Fluroquinolones (Ciprofloxacin) vs penicillin (Ampicillin sulbactum)	RR-1.17	RR-4.25	RR-0.09	Insufficient data to provide good evidence

One study , 81 women	Fluroquinolones(Ciprofloxacin) vs cephalosporin (cefotetan)	RR-1.29	RR-2.15	RR-0.0	Insufficient data to provide good evidence
One study, 88 women	Lincosamide (clindamycin) + aminoglycoside (Gentamycin) vs penicillin (Benzyl penicillin)	RR-1.46	RR-0.55	RR-0.0	Insufficient data to provide good evidence
Two studies, 118 women	Beta-lactum (Azithromycin , imipenum) vs cephalosporin (cefazolin, cefotamine)	RR-1.18	RR-0.39	RR0.0	Insufficient data to provide good evidence
One study , 241 women	Aminoglycoside plus nitroimidazole (gentamycin +metronidazole) vs standard cocktail of antibiotic	RR-0.81 CI- 0.29 to 2.26	RR-3.23 CI- 0.34 to 30.64	RR-1.08 CI- 0.07 to 17.03	No significant difference between two groups of antibiotics

Single-dose therapy has been proven to be effective when compared to multidrug group in most of the studies. It reduces the costs, potential toxicity, and the development of antibiotic resistant microorganism. Therefore, a single dose of an effective antibiotic, like a first generation cephalosporin, is the first-line drug of choice in CD as prophylaxis. If the patient is allergic to penicillin or cephalosporin, a single dose of clindamycin with an aminoglycoside is an alternative drug of choice for prophylaxis in CD.

ACOG Guidelines for recommendation of antibiotic prophylaxis in CD (82):

ACOG Level 1 Evidence: Recommendation for antibiotic prophylaxis in CD, a single dose of targeted antibiotic, such as a first-generation cephalosporin, is the first line drug of choice, unless there is significant drug allergy present.

SOGC clinical practice guideline recommendation for antibiotic prophylaxis in CD :

SOGC Level 1 Evidence: Recommendation : all women undergoing elective or emergency CD should receive prophylactic antibiotic and the choice of antibiotic is a single dose of a first generation cephalosporin .In addition, it is recommended that if the procedure extended for more than 3 hours or if the estimated blood loss was >1500ml, an additional dose of the prophylactic antibiotic may be given 3 to 4 hrs after the initial dose and the dose of antibiotic could be doubled if the patient was morbidly obese.

NICE guidelines(91):

Prophylactic antibiotic should be offered to all women at CD to reduce the risk of postoperative infection. The choice of antibiotic should be an antibiotic which is effective against endometritis, wound infection and urinary tract infection, which occur in about 8%of women who have had a CD.

WHO recommendation for antibiotic prophylaxis at CD(92)**:**

Ampicillin and first generation cephalosporins show similar effectiveness in all the main outcomes such as endometritis , febrile morbidity, wound infection ,urinary tract infections ,hence it is not justified to use other antibiotics with extended spectrum or multiple drugs.

The Swedish society of Gynaecology and Obstetrics guidelines for Antibiotic prophylaxis :

The antibiotic should have adequate tissue concentration, high safety, acceptable ecologically, easily administered , low cost and recommended cephalosporin group as a first drug of choice.

Time of Administration of prophylactic antibiotic in CD :

The Cochrane systematic review in 2014 analysed 12 trials, based on high quality evidence ,the preoperative administration of prophylactic antibiotic for CD significantly decreases the postpartum infectious morbidity like endometritis, wound infection, urinary tract infection when compared to administration of antibiotic post cord clamp and there is no adverse outcome on the neonates(86).In Uganda , Dlamini LD et al found that administration of prophylactic antibiotic one hour pre incision at CD, reduced the overall postoperative infectious morbidity, especially endometritis ,with a p value of 0.036(87). Baaqeel and Baaqeel et al found that preoperative prophylactic antibiotic significantly reduced the endometritis rate upto 41% and decreasing the other infectious morbidity like SSI and maternal febrile morbidity ,

which is not statistically significant and there is no significant neonatal adverse outcome in this group(88).Kaimal et al showed , that there was a significant reduction in the number of post Cesarian SSI which made the institution change it's policy and administer the pre incision prophylactic antibiotic in CD (89). CDC recommends antimicrobial prophylaxis to be administered according to guidelines and to be administered within 1 hr before the skin incision to attain maximum tissue concentration (66).Most of the guidelines ,with level A evidence recommend , that prophylaxis should be administered 60 minutes before the start of CD and there was no significant neonatal risks or antibiotic resistance to other microorganism(67,83–85)

Chuanzhang et al have done a multicentre randomized controlled trial and meta analysis in a Chinese population regarding the time of administration of antibiotic at CD and it was found that there was no statistically significant difference in endometritis, Hence it was recommended that both , preincision or an after cord clamping administration of prophylactic antibiotic at CD and the long term follow up of the neonates is needed (93).

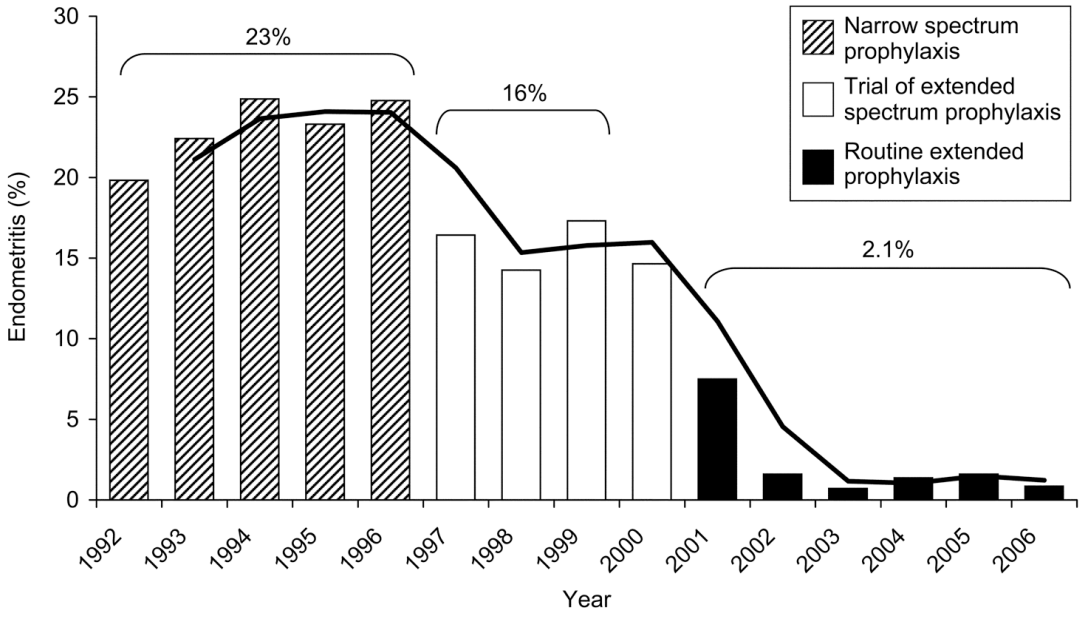
Prophylactic intravenous antibiotics administered before incision at Cesarian versus after neonatal umbilical cord clamping (94)**:**

Outcome **Effect size**	**No.of studies**	**No.of. Participants**	**Statistical method**
Endomyometritis			
Cephalosporin 1 gm	10	5041	Risk Ratio (M-H,fixed,95%CI) 0.54(0.36,0.7
Cephalosporin 1 gm	5	2144	Risk Ratio (M-H,fixed,95%CI)0.58 (0.30,1.12)
Cephalosporin 2 gm	5	2807	Risk Ratio (M-H,fixed,95%CI) 0.51(0.33,0.8
Wound infection			
Cephalosporin 1 gm	10	5041	Risk Ratio (M-H,fixed,95%CI) 0.59(0.44,0.81)
Cephalosporin 1 gm	5	2144	Risk Ratio(M-H,fixed,95%CI)0.55(0.30,1.01)
Cephalosporin 1 gm	5	2897	Risk Ratio (M-H,fixed,95%CI) 0.61(0.43,0.88)
UTI			
Cephalosporin 1gm	8	4001	Risk Ratio (M-H,fixed,95%CI) 1.02(0.65,1.59)
Length of hospital stay			
Cephalosporin 1 gm	2	1342	Mean difference (IV,Fixed,95%CI) 0.17(-0.30,-0.04)

Rationale for the use of extended spectrum antibiotic:

Despite the widespread use of prophylactic antibiotics, postpartum endometritis remains a common complication following CD, about 10-20 %(38).These infections are polymicrobial in nature ,which includes aerobes, anaerobes, ureaplasma or mycoplasma(37).There is a 3-8 fold increased risk of endometritis and wound infection if the amniotic fluid or chorion has ureaplasma urealyticum at the time of CD and the risk of endometrtis is 6 fold, if associated with bacterial vaginosis (32,40,91).The first generation cephalosporins does not cover the ureaplasma urealyticum which is one of the most frequent microorganism responsible for endometritis, and the narrow spectrum antibiotic modifies the microorganism and increases the resistant organism like anaerobes (37,92).Therefore adding an extended cover antibiotic such as metronidazole, clindamycin or azithromycin is rational. Newton et al found that cefazolin and ampicillin prophylax is altered the endometrial and endocervical flora in patients with endometritis. Inspite of this, there is no difference in the cure rate. This warrants an addition of extended spectrum of antibiotic (29).In a cohort study done by Tita et al, it was found that the addition of azithromycin to standard narrow spectrum antibiotic as prophylaxis in CD significantly decreased the incidence of endometritis (93). It has been proven that the use of an extended spectrum antibiotic with coverage of ureaplasma urealyticum like azithromycin and doxycycline as a prophylaxis in CD decreased the incidence of endometritis, wound infection and hospital stay in a randomized clinical trial when compared with cephalosporins alone (41).In a retrospective observational study over 3 consecutive periods Alan T.N Tita found that administration of extended spectrum

antibiotic with azithromycin significantly reduced the post CD infectious morbidity from 3.1% to 2.4% then 1.3% with P value of < .002 and post CD endometritis from 19.9% to 15.4% then 6.3% with p value of <0.001(93,94).



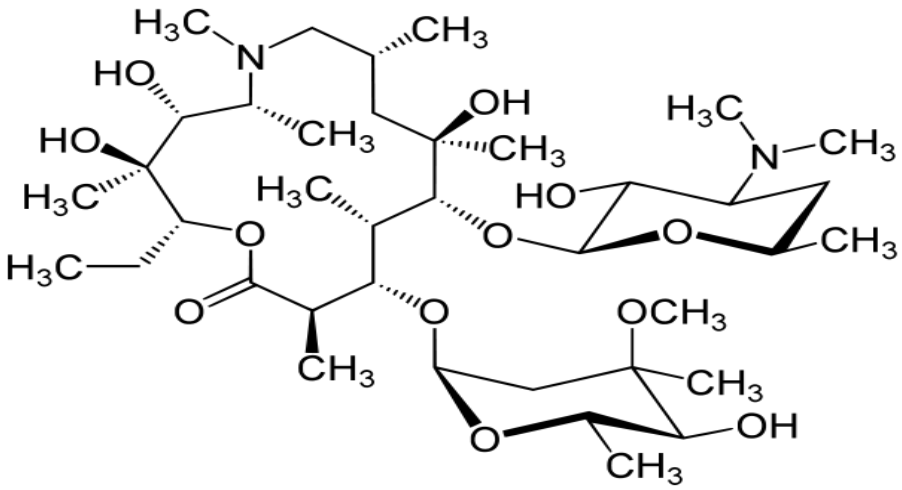
Tita et al, 2003

Overview of published data on extended spectrum antibiotic prophylaxis:

Study	Design	sample size	Antibiotics	Endometritis	SSI	Hospital stay
O'Leary 1986	**RCT**	**123**	**Gentamycin (+Ampicillin)**	**0.38(0.14,0.99)**	**0.98(0.06,15.0)**	**1.4 days shorter**
Pitt, 2001	**RCT**	**224**	**Vaginal metronidazole (+Cefazolin)**	**0.42(0.19,0.92)**	**1.67(0.41,6.81)**	**No difference**
Meyer, 2003	**RCT**	**160**	**Metronidazole (+Cefotetan)**	**0.43(0.23,0.82)**	**N/A**	**1.4 days shorter**
Andrews, 2003	**RCT**	**597**	**Azithromycin/ Doxycyline (+cefotetan)**	**0.68(0.49,0.94)**	**0.22(0.05,0.99)**	**½ days shorter**

Why should Azithromycin be used?:

$C_{38}H_{72}N_2O_{12}$



Azithromycin belongs to the azalide macrolides group of antibiotic which has a similar action to erythromycin. It has a broad spectrum of activity which covers aerobic, gram positive anaerobic, intracellular microorganism. Azithromycin binds to the 50S subunit of the 70S bacterial ribosomes, therefore it inhibit RNA-dependent protein synthesis. Approximately 37% of the antibiotic is absorbed after an oral dose of 500mg, and the peak level occurs within 6 hrs of administration. Azithromycin has larger volume of distribution of about 23L/Kg and low serum level of 0.4microgram /ml , a prolonged half life and increased tissue levesl of about 68hr and the intracellular concentration of the term pregnant women. Azithromycin metobolise through hepatic biliary excretion(95–97).Azithromycin levels are seen in high concentration in maternal uterine myometrium, adipose tissue and placenta and remains stable for upto 72hrs. The serum level of azithromycin in umbilical artery and vein were low and could be safely used to treat perinatal infections(98).Adverse effects of the drug includes nausea, vomiting ,abdominal pain and prolongation of QT interval in the older patient . Sutton et al found that ,a single dose of 500mg

intravenous azithromycin before CD attained effective maternal plasma concentration more than MIC50 for most ureaplasma spp, and it had adequate plasma , myometrial concentration against ureaplasma urealyticum and it could be given >1hr before skin incision in CD as a prophylaxis for wound infection (99).

Rationale for this study

Studies have shown that administration of extended spectrum antibiotic along with narrow spectrum as prophylaxis for CD has decreased the incidence of post infectious morbidity, but not many studies have specifically compared extended spectrum antibiotic use with standard narrow spectrum antibiotic with standard narrow spectrum antibiotic alone prior to skin incision. Therefore this randomised trial was designed to study the efficacy of prophylactic antibiotic at CD in preventing post CD infectious morbidity and the maternal outcome.

If this study can prove that administration of extended spectrum antibiotic along with standard narrow spectrum antibiotic pre incision and post CD infectious morbidity are less without any adverse effect on mother and baby, the present practice of administering narrow spectrum prophylactic antibiotics at cesarian delivery can be changed.

METHODS

Design

This was a randomised, double blinded, controlled trial.

Setting

The study was carried out at the Christian Medical College, Vellore in the Department of Obstetrics and Gynaecology . The study was conducted in the labour room, outpatient department and post natal wards of the department. This is a tertiary care hospital situated in Vellore, a town in south India.

All mothers more than or equal to 37 completed weeks of gestational age were randomised to the study protocol once the decision was made for CD.

Participants:

All women more than or equal to 37 completed weeks of gestation delivered by CD in Christian Medical College and Hospital Vellore were included in this study.

Informed consent

Informed consent was taken from patient or the relatives once the decision was made for CD (Patient information sheet and sample consent form – Annexure)

Key criteria

Inclusion Criteria:

All women of 37 completed weeks of gestation or more delivered by Cesarian delivery in Christian Medical College and Hospital Vellore were included in this study.

Exclusion Criteria:

1. Mothers with known allergy to Cephalosporin / Penicillin.

2. Mothers who have received antibiotics within a week prior to the delivery or on antibiotic for GBS prophylaxis or chorioamnionitis.

3. Mothers with altered liver function (serum total bilirubin >3mg/dL).

4. Mother with renal dysfunction (serum creatinine >1.5mg/dL).

5. Mothers on medications such as carbamazepine or phenytoin.

6. Unable to take consent due to emergency CD(cord prolapsed, doubtful scar integrity)

Intervention and comparator drugs

Intervention:

Women undergoing CD were randomised according to the drug number to receive both injection cefazolin 1 gm iv and the study drug(Azithromycin or placebo) prior to skin incision.

Comparator:

Injection cefazolin and placebo prior to skin incision

Ethics clearance:

The study was approved by the Institutional Research Board and Ethics committee.(Annexure 4)

Methodology:

This was a randomised, double blinded, controlled trial, where mothers were randomised to the study protocol once they the decision was made for CD. Each of the randomised woman received two injections prior to skin incision (Inj. cefazolin along with study drug or Inj. Cefazolin with a placebo) according to the randomisation code. After CD, these women were monitored in the ward for evidence of infection or any adverse event the drug might have caused. They were followed up till 42 days post delivery for any infectious morbidity (surgical site infections, urinary tract infection and readmission).

Patient information sheet and consent forms for the clinical trial were kept along with the consent form for the CD in the labor room.. Consent for the elective CD was taken during the antenatal visits in the outpatient department and consent for the emergency CD and the unbooked women was taken at admission into the labour room.

The sample size was calculated to be a total of 1996 women participants. They were randomised to 2 groups, group 1,consisting of 998 mothers to receive IV cefazolin 1 gm (>80kg-2gm) and IV Azithromycin 500 mg in 250 mL NS over 1 hour pre incision. Group 2 ,to have 998 mothers who will receive IV Cefazolin 1gm and IV placebo in 250mL NS over 1 hour pre incision, according to computer generated randomisation drug number.

After the CD, the mother was to be followed up in the postnatal ward upto discharge, and untill 6 weeks postpartum for the following outcome measures.

The primary outcome measures in the mother were the following: infectious morbidities- post operative surgical site infection, endometritis, UTI and length of the hospital stay.

Endometritis was diagnosed according to CDC guidelines: maternal fever >100.4^{0}F on 2 separate occasions with uterine fundal tenderness, or foul smelling vaginal discharge. Urinary tract infection was diagnosed according to urine culture. and sensitivity reports. SSI was diagnosed according to CDC guidelines and the length of hospital stay was calculated from the time of delivery until discharge form the hospital.

Mother were advised to follow up at the end of 42 days for the routine postnatal review or earlier if they had any fever, symptoms of urinary tract infections, pus or serous discharge from the operated site, redness ,swelling or wound gaping. Those who were unable to attend the postnatal review at the end of 42 days were called by

the principle investigator and enquiries made about their well being and about any of the above symptoms and the treatment for the same.

Target sample size and rationale

The sample size to compare the effect of extended spectrum antibiotic along with standard antibiotic on the rate of infection in the mother was found to be 996 in each arm with 90% power, at 5% level of significance, an anticipated difference of 9% (based on a study done by Tita et al) as mentioned earlier with a 20% loss to follow up.

Formula:

$$n = \frac{\left(Z_{\alpha/2} + Z_{1-\beta}\right)^2 2PQ}{d^2}$$

Where P=0.235Q=0.765

$\mathbf{Z_{\alpha/2}}$is the alpha level of significance$\mathbf{Z_{1-\beta}}$ is level for 90% power d = p1-p2P = average of p1 and p2

Method of randomization

Computer generated block randomization sequence

Method of allocation concealment

Serially numbered opaque envelopes with the treatment allocation were provided to the Principle Investigator which were opened at the time of treatment administration .

Blinding and masking:

The participant , the care givers and the Principle investigator (who is the outcome assessor) were blinded to the treatment allocation .

Data Analysis

Data entry was done into Microsoft Excel spreadsheets and Epidata software.

Analysis was done using SPSS 16 software. Mean and standard deviation were calculated for normally distributed data. Appropriate tests for significance –Chi square test, Levene's Test for Equality of Variances, t-test for Equality of Means were performed.

Adverse effects with IV Cefazolin and IV Azithromycin were thought to be unlikely. However, monitoring was done after administration of the drug. All data was submitted to the institutional Data Safety Monitoring Board for review at the interim period and at the end of the trial.

Validation of Drugs used in the Trial

The drug Cefazolin and Azithromycin are commonly given during pregnancy and hence it was considered to be safe to administer to the mother, and not sent for validation. The results were not known to the investigators treating team, the caregivers / nursing staff or the patient's family.

Data Safety Monitoring Board

The results were presented to the DSMB for their approval.

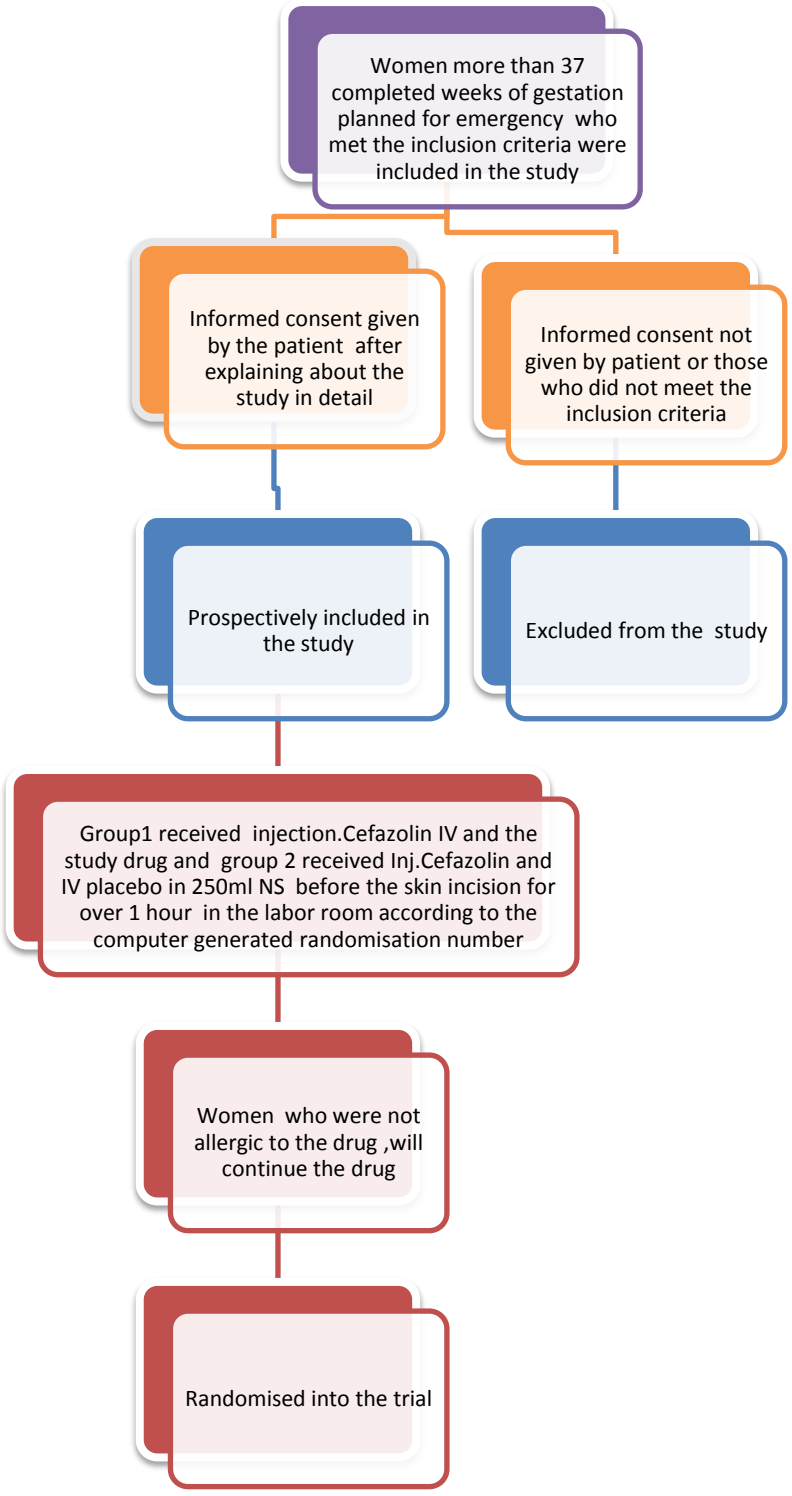


Figure1 :Schematic representation of the trial

Figure 1: Shows that mothers were randomised to the study protocol once they the decision was made for CD were told about the study in detail and informed consent was taken from the patients who met the inclusion criteria. After obtaining the informed consent, patient were included in the study and the rest were excluded from the study.

Women ,who were included in the study would be given injection cefazolin IV and the study drug in 250 ml NS for 1 hr in the labor room(either the placebo or the drug) according to the computer generated randomisation number, prior to skin incision .In women who had allergy to the drugs ,it was discontinued and patient was excluded from the study(As represented in figure 1 above).

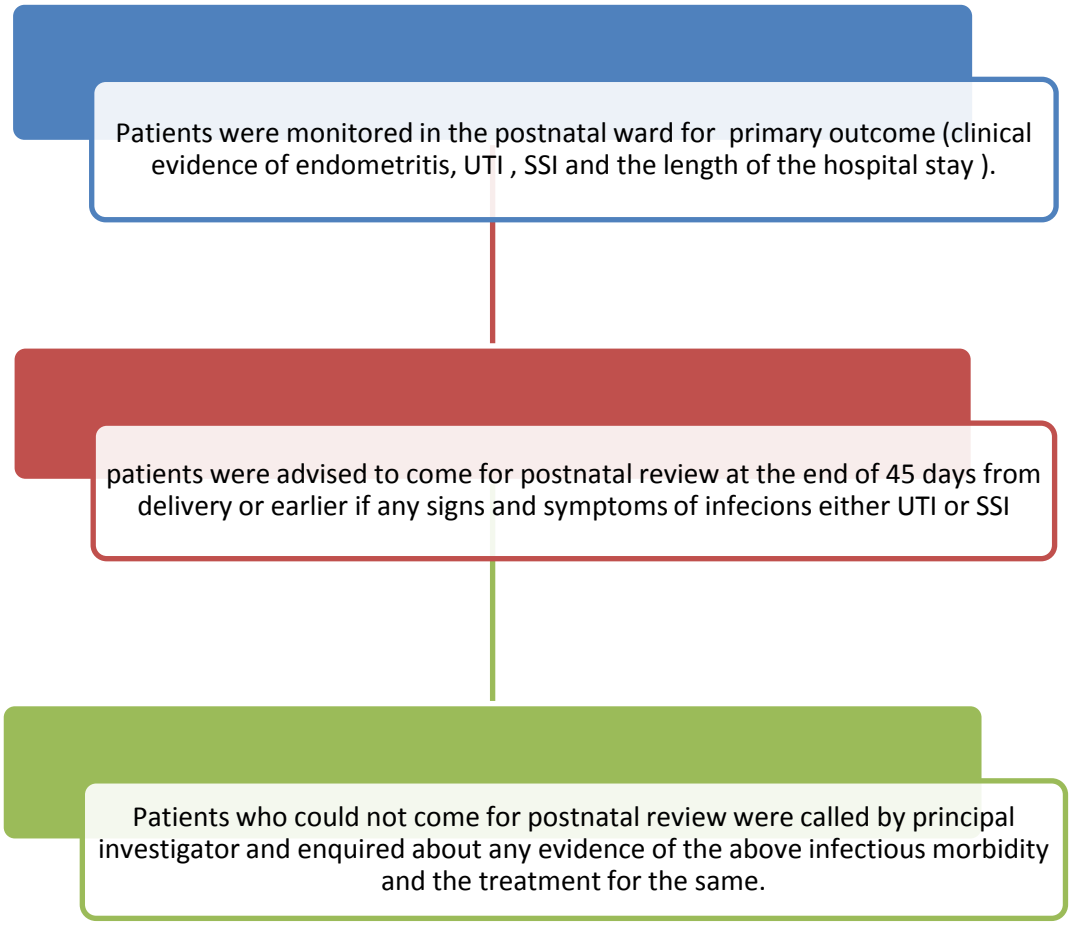


Figure 2: Schematic representation of follow up of the patients

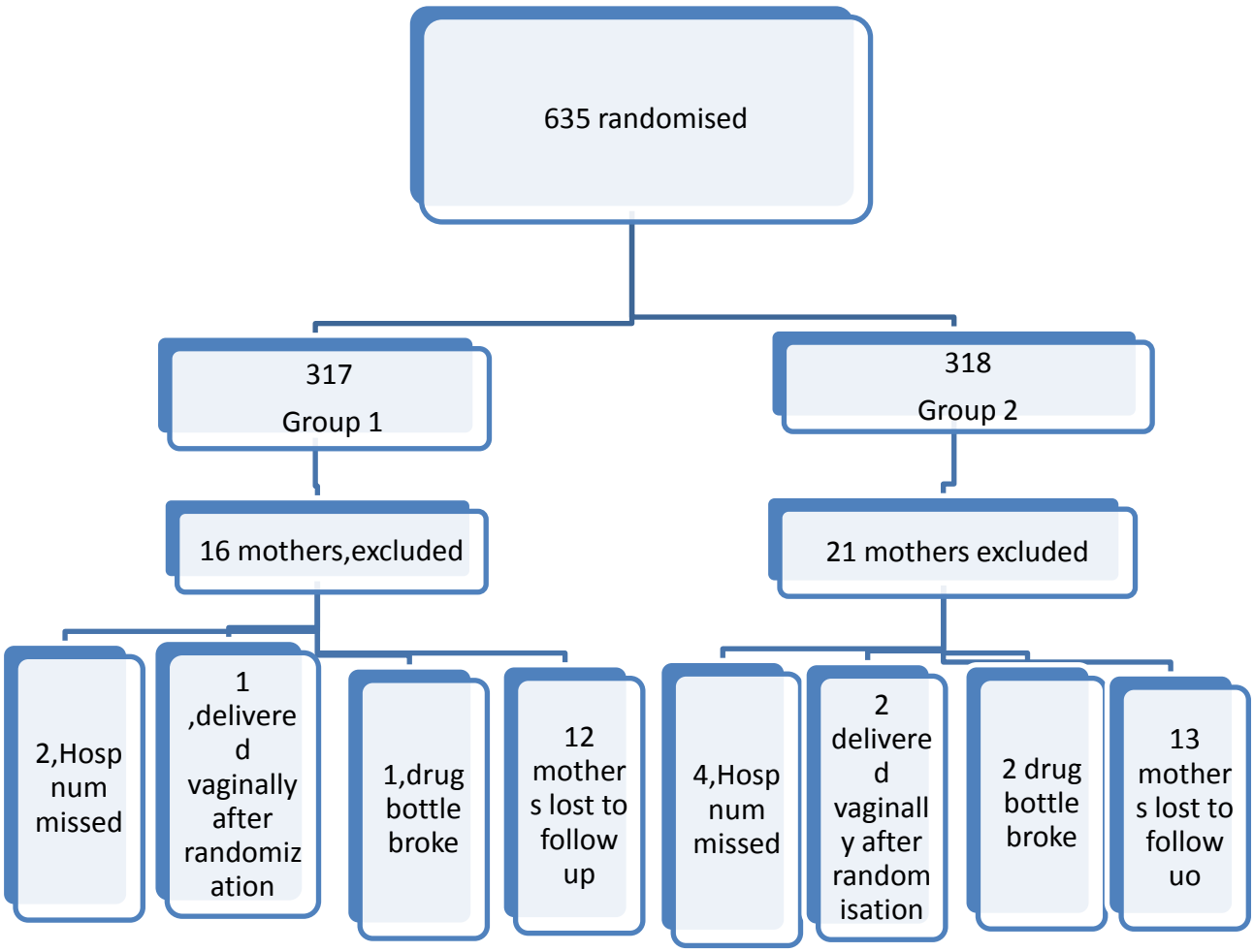
Figure 2 : Shows the follow up of the study patients. They were monitored in the postnatal wards during their hospital stay and evidence of endometritis, surgical site infection , urinary tract infection, length of hospital stay were recorded.

Patients once discharged from the hospital were advised review at the end of 6 weeks postpartum or earlier if there is any signs and symptoms of Endometritis, urinary tract infection and SSI.

Patients who could not report at the end of 6 weeks postpartum were called by principal investigator and enquired about any signs and symptoms of urinary tract infection and SSI and the treatment taken for the same.

RESULTS

A total of 635 patients were recruited into the study over a period of 5 months(March 2015 to July 2015).The consort diagram is given below. Out of the total 635 patients that were enrolled, the serial number of the enrolment drug was inadvertently missed in 6 of them. Three patients who were expected to have CD, delivered normally after randomization, and in another 3 ,the drug bottles were accidently broken. Twenty five of the women were lost to follow up due to various reasons. Among 598 mothers included in the analysis ,302mothers in Group 1, received extended spectrum antibiotic along with standard narrow spectrum antibiotic(Inj. Azithromycin with Inj.cefazolin)and 296 mothers in Group 2, received standard narrow spectrum antibiotic with placebo(Inj.cefazolin with placebo).


635 randomised
317
Group 1
318
Group 2
16 mothers,excluded
21 mothers excluded
2,Hosp num missed
1 ,delivered vaginally after randomization
1,drug bottle broke
12 mothers lost to follow up
4,Hosp num missed
2 delivered vaginally after random isation
2 drug bottle broke
13 mothers lost to follow uo

Demographic Characteristics of the study population Distribution of the age of the women:

Table 1 :Distribution of the age of the women

	Group 1	Group 2	Total	P value
No.of patients	302	296	598	
Mean age	27.59	27.28	27.43	
SD	4.38	4.65	4.51	0.373
Minimum age	17	17	17	
Maximum age	39	40	40	

In this study, there were 302 patients in group 1, and 296 in group 2.The mean age in group 1 was 27.59 years and the standard deviation was 4.38.The mean age in group 2 was 27.28 years and the standard deviation was 4.65 (P value - 0.373).There was no significant difference between the maternal ages in both groups.

Distribution of the Gestational age at CD:

Table 2 : Distribution of gestational age :

	Group 1	Group 2	Total	P value
No.of patients	302	296	598	0.721
Mean	38.71	38.74	38.7	
SD	1.13	1.06	1.09	
Minimum gestational age	37 weeks	37 weeks	37 weeks	
Maximum gestational age	41 weeks	42 weeks	42 weeks	

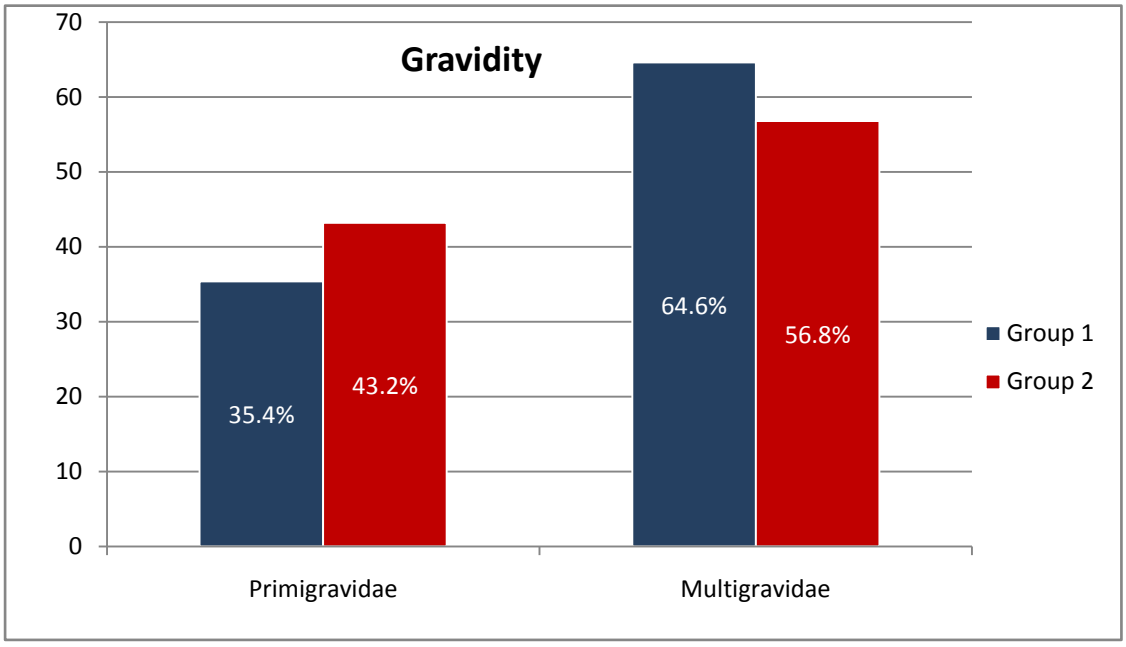
Overall, the mean gestational age was 38.7 weeks and the standard deviation was 1.09. The maximum gestational age was 42 weeks and minimal gestational age was 37 weeks. In group 1, there were 302 patients; the mean gestational age was 38.71 weeks with a standard deviation of 1.13. The maximum gestational age was 41 weeks and minimum gestational age was 37 weeks. In group 2, there were 296 patients, the mean gestational age was 38.74 weeks, with standard deviation of 1.06. The maximum gestational age was 42 weeks and minimum gestational age was 37 weeks (P value 0.721).There was no difference in the gestational ages between the groups.

Distribution of gravidity:

Table 3 : Distribution of women according to gravidity

Gravidity	Group 1	Group 2	Total	P value
Primigravidae	107 (35.4%)	128 (43.2%)	235(39.3%)	0.054
Multigravidae	195 (64.6%)	168 (56.8%)	362(60.7%)	
Total	302	296	598	

Figure 1: Distribution of women according to gravidity



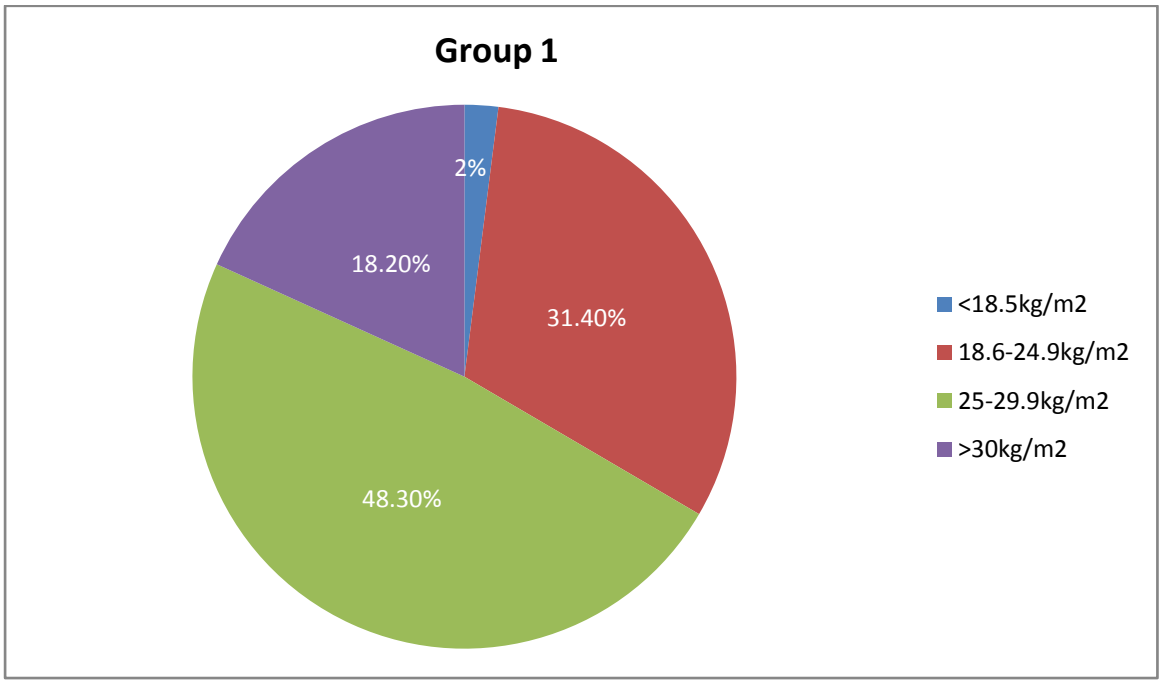
There were 235(39.3%) primigravid and 363 (60.7%) multigravid women in the study. Ingroup 1,there were 107(35.4%) primigravidae and 195 (64.6%) multigravidae, when compared to 128(43.2%) primigravidae and 168(56.8%) multigravidae in group 2. There were significantly more number of multigravidae, when compared to primigravidae (P value- 0.054).

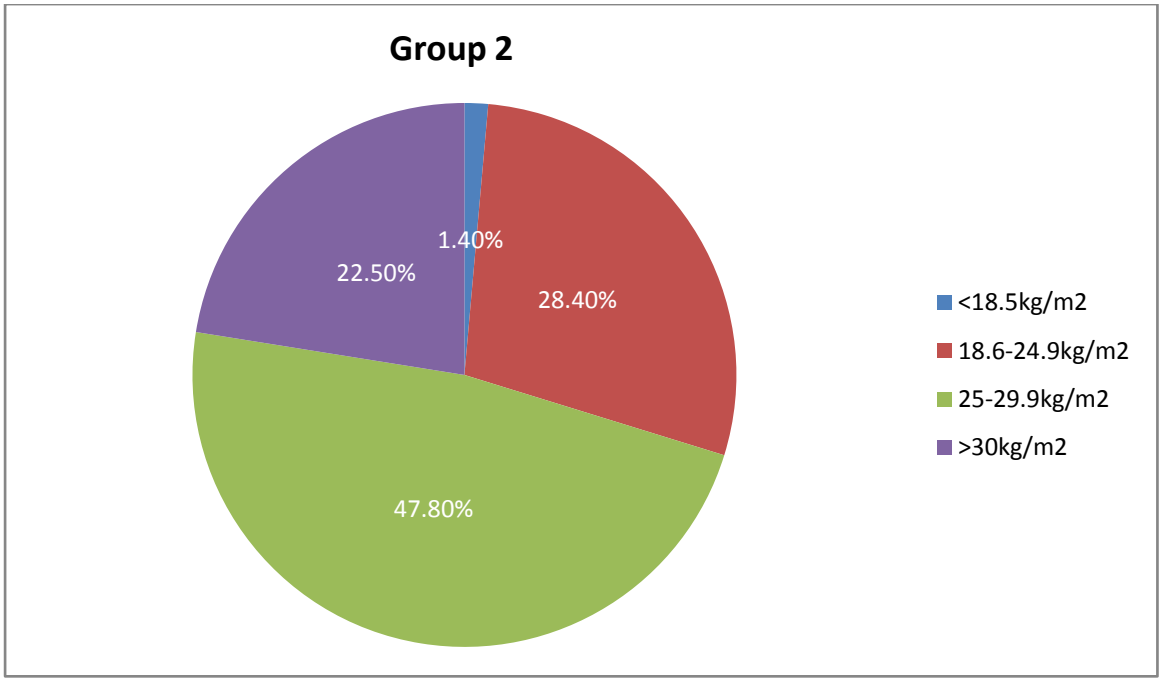
Distribution of BMI

Table 4:Distribution of BMI

BMI	Group 1	Group 2	Total	P Value
<18.5kg/m2	6(2.0%)	4(1.4%)	10(1.7%)	
18.5-24.9kg/m2	93(31.4%)	82(28.4%)	175(29.9%)	
25-29.9kg/m2	143(48.3%)	138(47.8%)	281(48.0%)	
>30kg/m2	54(18.2%)	65(22.5%)	119(20.3%)	0.549

Figure 2 :Distribution of BMI





The body mass index (BMI) was calculated from the recorded weight at first antenatal visit, as most of them did not know their pre pregnancy weight. There were 10 (1.7%) women in group 1, and 6(2.0%) in group 2 who fell into the underweight category. In the normal weight category, there were 93(31.4%) women in group 1 and 82(28.45%) in group2. The overweight category had 143(48.3%) in group1 and 138(47.8%) in group 2, whereas in the obese category there were 54(18.2%) women in group1 and 65(22.55%)in group2.

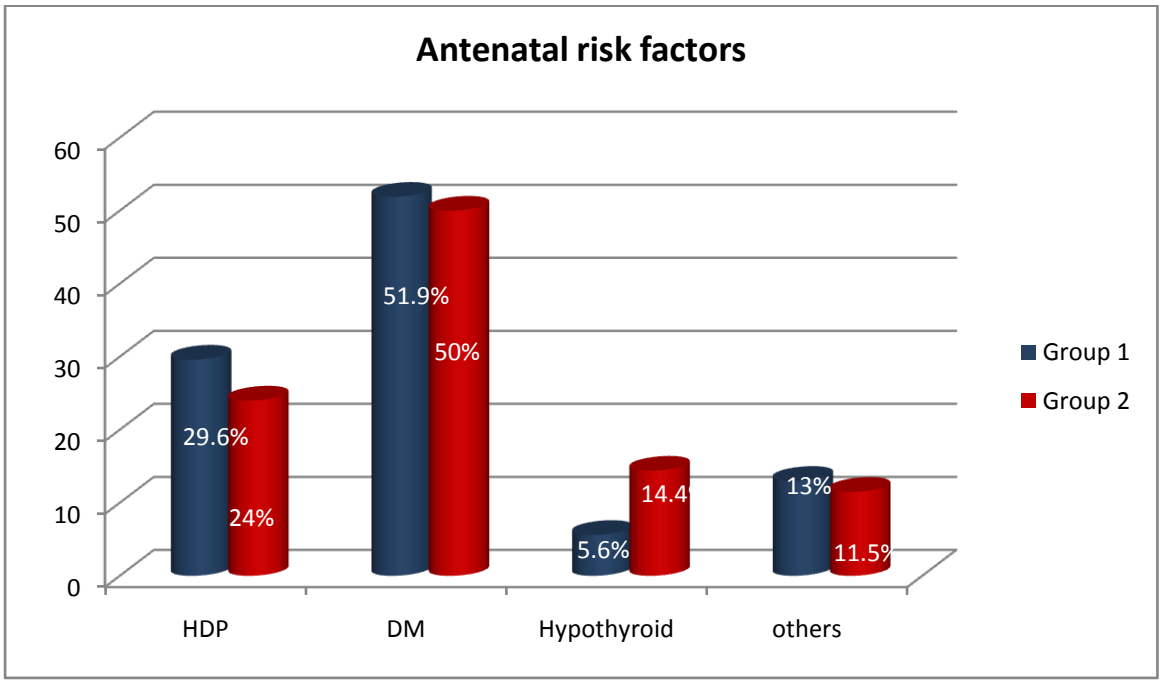
Obstetric Risk factors-Univariate Analysis

Prevalence of Antenatal risk factors in study population

Table 5 : Prevalence of Antenatal risk factors:

Antenatal risk factor	Group 1	Group 2	Total	P value
HDP	32(29.6%)	25(24.0%)	57(26.9%)	0.176
Diabetes	56(51.9%)	52(50.0%)	108(50.9%)	
Hypothyroid	6(5.6%)	15(14.4%)	21(9.9%)	
Others	14(13.0%)	12(11.5%)	26(12.3%)	
No risk factors	194(32.4%)	192(32.1%)	386(64%)	

Figure 2:Prevalence of Antenatalrisk factors



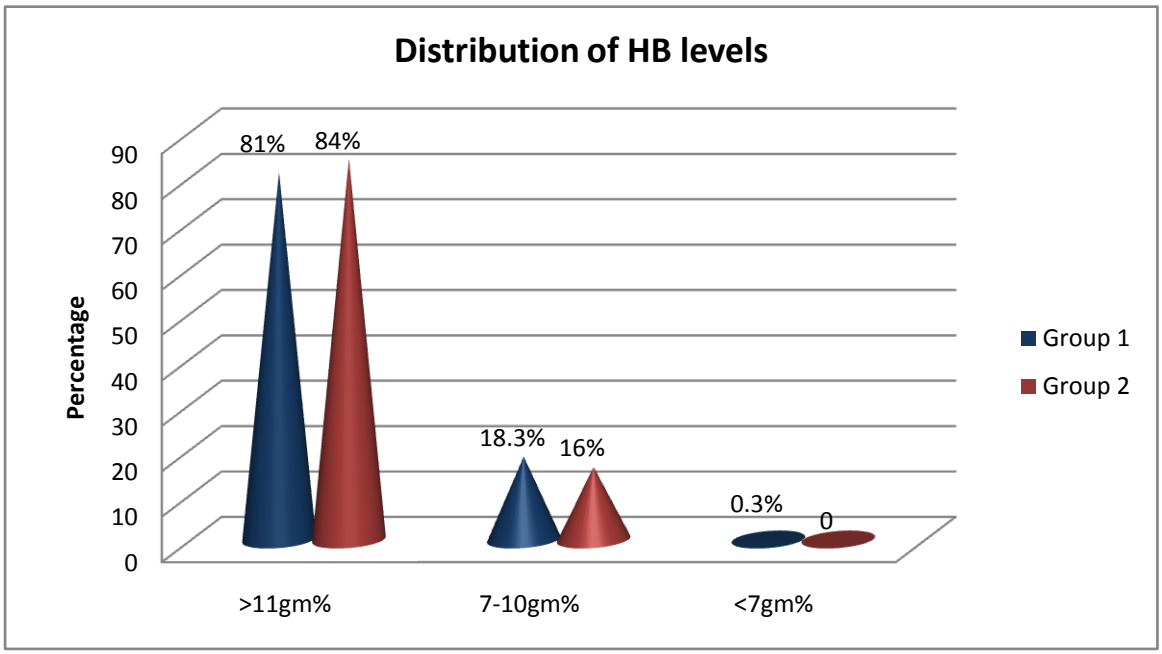
There were 57(26.9%) women with hypertensive disease of pregnancy (HDP).This included pre- eclampsia, eclampsia, chronic hypertension, gestational hypertension and superimposed pre-eclampsia. In group 1,there were 32(29.6%) women and in group 2, 25(24%).There were 108 (50.9%) women with diabetes and this included pre gestational and gestational diabetes managed with medical nutritional therapy, oral hypoglycaemic agents and / or insulin. Group 1 had 56(51.9%) with diabetes and group 2had 52(50.0%). There were a total of 21 (9.9%) women with hypothyroidism complicating pregnancy ,6(5.6%) in group 1 and 15(14.4%) in group 2.A few diseases like bronchial asthma, tuberculosis treated, Hepatitis B Positive diseases were included under "others" and constituted 26 (12.3%) of the total, 14(13%) in group 1 and 12(11.5%) in group 2.There were 386(64.5%) women without any associated antenatal risk factors , 194(64.2%) in group 1 and 192(64.4%) in group 2.There were more HDP and diabetes disease complicating pregnancy in group 1 compared with group 2 ,but it was not statistically significant

Distribution of Hemoglobin (Hb) levels:

Table6 : Distribution of Hemoglobin levels:

Hb	Group 1	Group 2	Total	P value
>11gm%	244(81.3%)	247(84.0%)	491(82.7%)	0.453
7-10.9gm%	55(18.3%)	47(16.0%)	102(17.2%)	
<7gm%	1(0.3%)	-	1(0.2%)	

Figure 3: Distribution of Hemoglobin levels:



There were 491(82.7%) women with normal haemoglobin (> 11gm/dl) in all. This assessment was carried out at first antenatal visit, irrespective of the gestational age .In group 1, there were 244(81.3%) with normal Hb and in group 2 ,247(84%) . Mild and moderate anemia (Hb level between 7and10.9gm/dl) was present in, 55(18.3%) of group 1 women and 47(16%) of group 2.There was one patient with severe anaemia in group 1 ,none in group 2 .

Duration ofprelabour Rupture of membranes (PROM)

Figure 4: Duration of PROM:

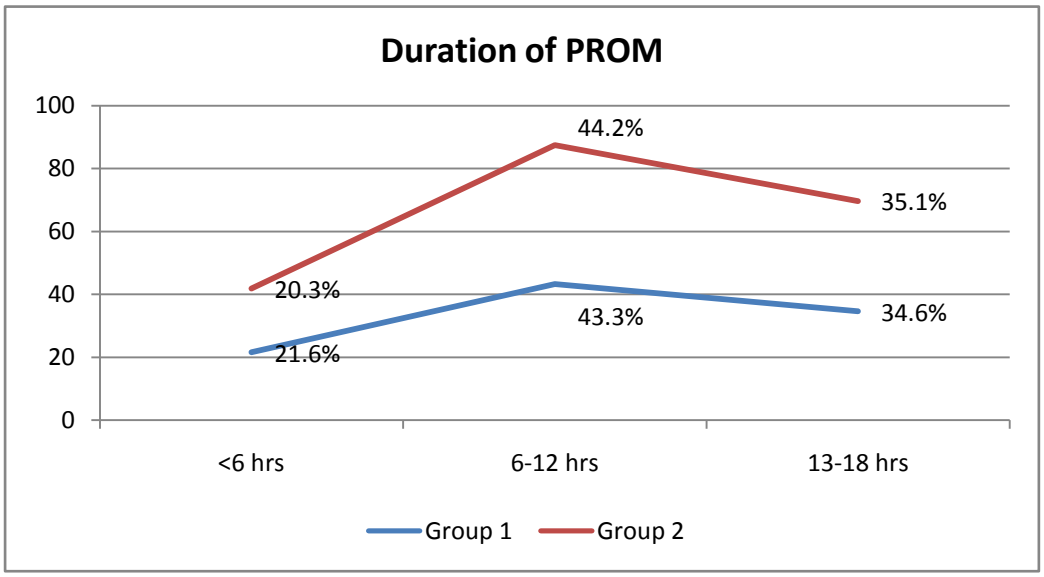


Table7 : Duration of PROM

Duration of rupture of membrane	Group 1	Group 2	Total	P value
<6hrs	29(21.6%)	28(20.3%)	57(21.0%)	**0.944**
6-12hrs	58(43.3%)	61(44.2%)	119(43.8%)	
13-18hrs	47(34.6%)	49(35.1%)	96(34.8%)	

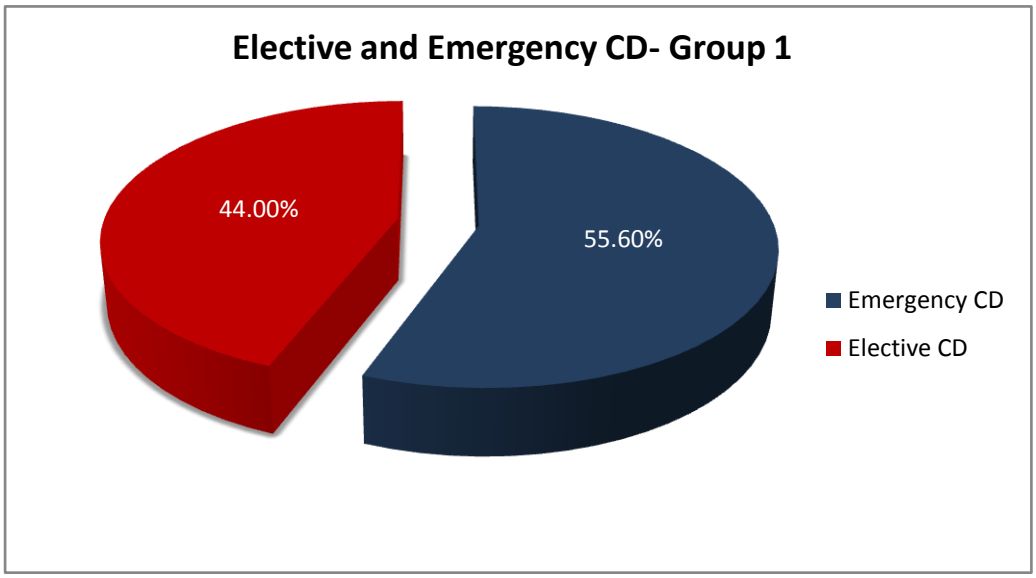
The duration of PROM was analysed in the study population. There were 29 (21.6%) patients in group 1 and 28(20.3%) patients in group 2 who had less than 6 hours of PROM .There were 58(43.3%)in group 1 ,61(44.2%) in group 2 who presented with 6-12 hours of PROM .Women who had 13 -18hours of PROM made up the remaining, 47(34.6%)in group 1 ,49(35.1)in group 2 . There was no significant difference between the 2groups.

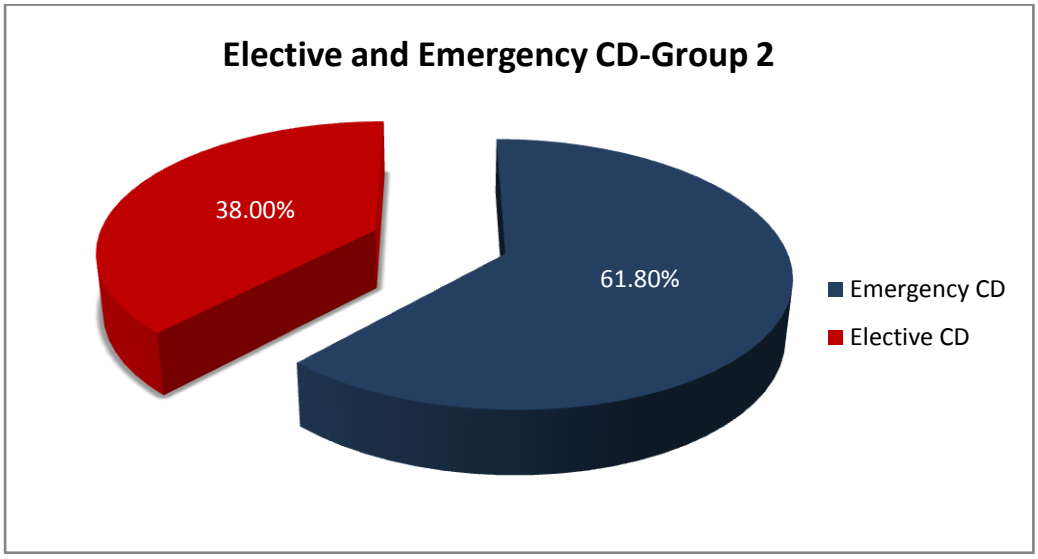
Distribution of Elective and EmergencyCD :

Table 8 : Elective and Emergency CD

Type	Group 1	Group 2	Total	P Value
Emergency CD	168(55.6%)	183(61.8%)	351(58.6%)	0.135
Elective CD	132(44.0%)	112(38.0%)	244(41.0%)	

Figure5 :Elective and Emergency CD





There were a total of 7,200 deliveries during the study period. The total number of CD during the same period was 2,100. There were 168(55.6%) patients in group 1 and 183(61.8%)in group 2 who underwent emergency CD. Of group 1,132(44%),and of group 2,112(38%) women had elective CD. The rate of emergency CD was more(55.6% and 61.8%)in groups 1 and 2,respectively,when compared with elective CD and the P value was 0.135.

Distribution of indications for CD

Table 9:Indications for emergency CD

Indication	Group 1	Group 2	Total	P value
NRFS	60(44.4%)	86(60.1%)	146(52.5%)	0.009
Abnormal Lie in labour	9(6.7%)	4(2.8%)	13(4.7%)	
Labour dystocia	27(20%)	12(8.4%)	39(14%)	
Failed induction	36(26.7%)	35(24.5%)	71(25.5%)	
Previous LSCS Declined TOLAC	25(75.8%)	20(50%)	45(61.6%)	
Breech with PROM	6(18.2%)	13(32.5%)	19(26%)	
IVF pregnancy	2(6.1%)	7(17.5%)	9(12.3%)	
Others	3(2.2%)	6(4.2%)	9(3.2%)	

Table 10: Indication for elective CD

Indication	Group 1	Group 2	Total	P value
Declined TOLAC	80(61.5%)	70(63%)	150(62.2%)	0.995
Breech presentation	20(15.4%)	18(16.2%)	38(15.8%)	
Non vertex 1st twin	4(3.1%)	2(1.8%)	6(2.5%)	
>1 Previous LSCS	13(10.0%)	11(9.9%)	24(10.0%)	
Inter delivery interval <18months	7(5.4%)	6(5.4%)	13(5.4%)	
Previous preterm LSCS	4(3.1%)	3(2.7%)	7(2.9%)	
IUGR with abnormal Dopplers	2(1.5%)	1(0.9%)	3(1.2%)	

When considering the indications for CD, the commonest was for non reassuring fetal heart (NRFS), 60(44.4%) in group 1 and 86(60.1%)in group 2 .Among the elective CD, the commonest indication was for those women with previous LSCS who declined Trial of Labour after Cesarian delivery(TOLAC) and they constituted80(61.5%)in group 1 and 70(63.1%)in group 2. On the whole, there were more number of emergency CD when compared to elective CD and this was statistically significant with a P value of 0.009.

Time duration for CD, intra operative blood loss, need for Peri operative blood transfusion-univariate analysis

Table 11 : Time duration for CD, intra operative blood loss and need for peri operative blood transfusion:

Time duration of surgery

Duration	**Group 1**	**Group 2**	**Total**	**P value**
<1 hr 1-2 hr >2 hr	288(96%) 11(3.7%) 1(0.3%)	286(97.3%) 7(2.4%) 1(0.3%)	574(96.6%) 18(3.0%) 2(0.3%)	**0.659**
Intra operative blood Loss				
<500mL 600 – 1000mL 1100 – 2000mL	252(84.0%) 44(14.7%) 4(1.3%)	234(79.1%) 60(20.3%) 2(0.7%)	486(81.5%) 104(17.4%) 6(1.0%)	**0.152**
Peri operative blood transfusion				
Yes No	6(2.0%) 295(98.3%)	8(2.7%) 285(94.2%)	14(2.4%) 573(96.3%)	**0.599**

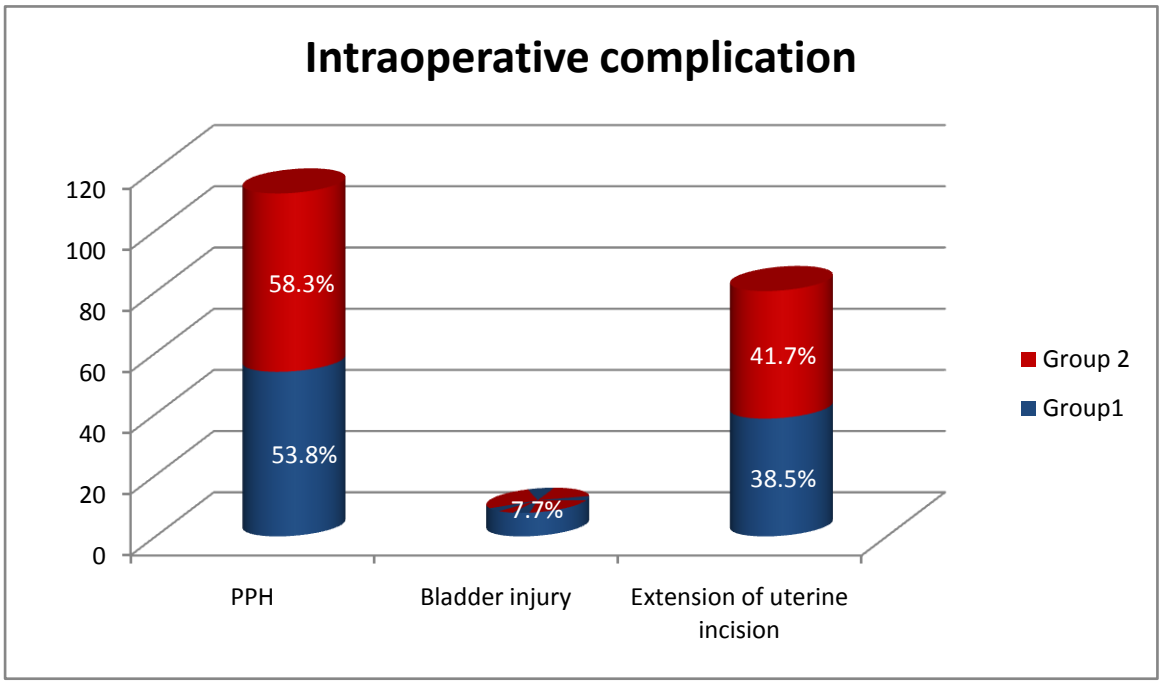
Univariate analysis was done for duration of surgery , intra operative blood loss, and the need for peri operative blood transfusion . Most of the CD were completed within one hour,288(96%)in group 1 and 286(97.3%) in group 2.Most of the women in both groups had blood loss less than 500ml, 252(84%) in group 1 and 234(79.1%) in group 2.There were 44(14.7%)women in group 1 and 60(20.3%) in group 2 who had blood loss between 600-1000ml and a small number who lost 1100-2000 ml , 4(1.3%) in group 1 and 2(0.7%)in group 2. Only 6(2%)in group 1 and 8(2.7%) women required blood transfusion.

Incidence of Intra-operative complications:

Table 12: Intraoperative complications :

Intraoperative complication	Group 1	Group 2	Total	P value
PPH	7(53.8%)	7(58.3%)	14(56%)	
Bladder injury	1(7.7%)	-	1(4.0%)	0.618
Extension of uterine incision	5(38.5%)	59(41.7%)	10(40%)	

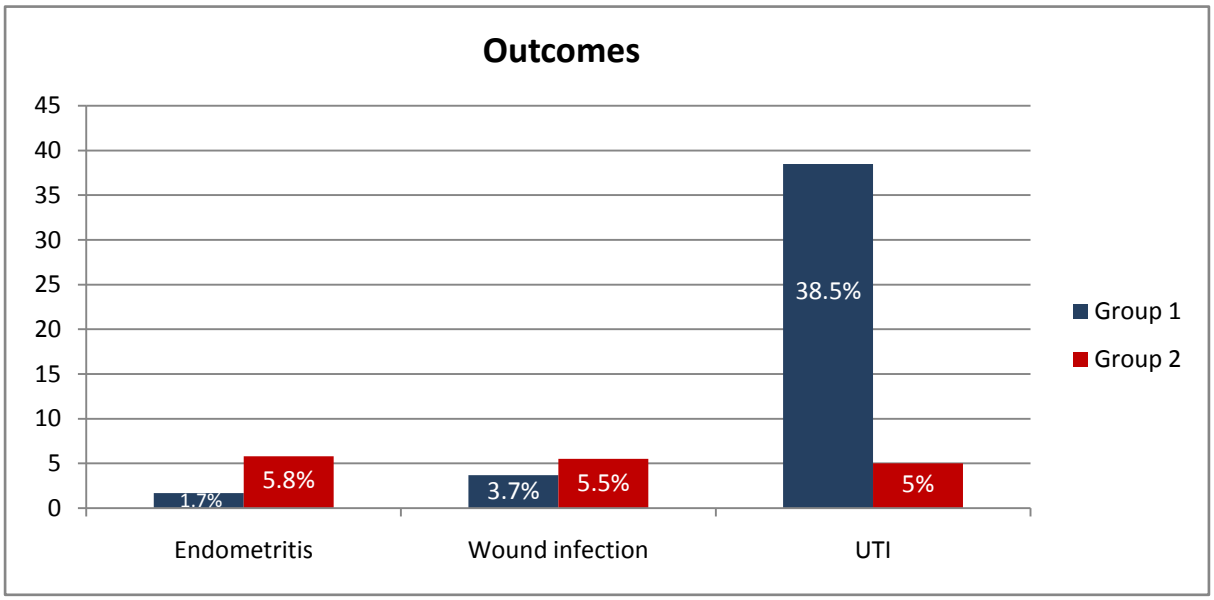
Figure 7:Intraoperative complication



When considering postpartum hemorrhage (PPH),group 1 had 7(53.8%) and 7(58.3%) in group 2 .In the present study,other intre-operative complications were related to extension of the uterine incision,which numbered 5(38.5%)in group 1 and 5(41.7%) in group 2.One patient had bladder injury in group 1.

Analysis of the Primary Outcomes

Figure8 :Evidence of endometritis,SSI and UTI



Evidence of endometritis

Table 13:Evidence of endometritis

Evidence of endometri	Group 1	Group 2	Total	P value
Yes	5(1.7%)	17(5.8%)	22(3.7%)	0.009
No	295(98.3%)	282(94.2%)	573(96.3%)	

On analysing the data ,it was found that there were a total of 22(3.7%) women with evidence of endometritis, 5(1.7%) in group 1 and 17(5.8%) in group 2. There was statistically significantreduction (p value of 0.009) of evidence of endometritis with the use of extended spectrum antibiotics as prophylaxis at CD.

Incidence of Surgical site infections(SSI)

Table 14: Surgical site infections

SSI	Group 1	Group 2	Total	P value
Yes	11(3.7%)	16(5.5%)	27(4.6%)	0.329
No	287(96.3%)	276(94.5%)	563(95.4%)	

The overall incidence of SSI in the study population was 27(4.6%) , of which, group 1 had11(3.7%) and group 2 had 16(5.5%). Eventhough it was not statistically significant the rate ,of SSI showed a trend towards lesser incidence of SSI with extended spectrum antibiotics.

Urinary tract infection (UTI):

Table 15:Incidence of urinary tract infection

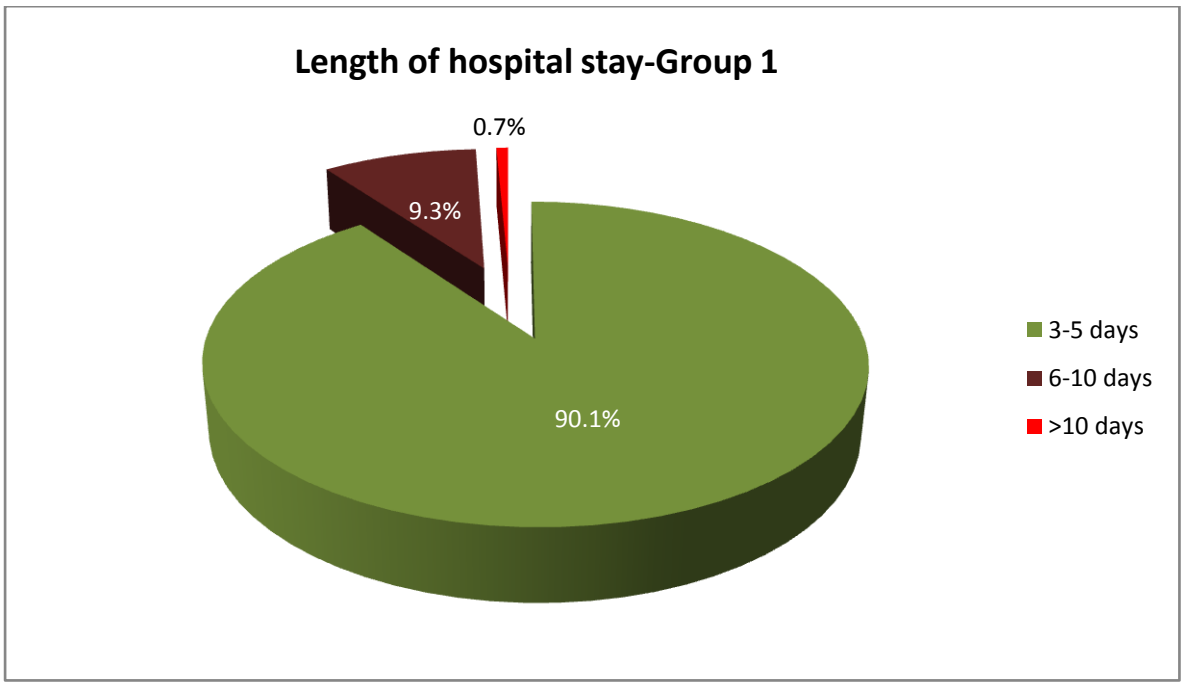
Incidence of Urinary tract infection	Group 1	Group 2	Total	P value
Yes	5(71.4%)	2(28.6%)	7(100%)	0.265
No	297(50.3%)	294(49.7%)	591(100%)	

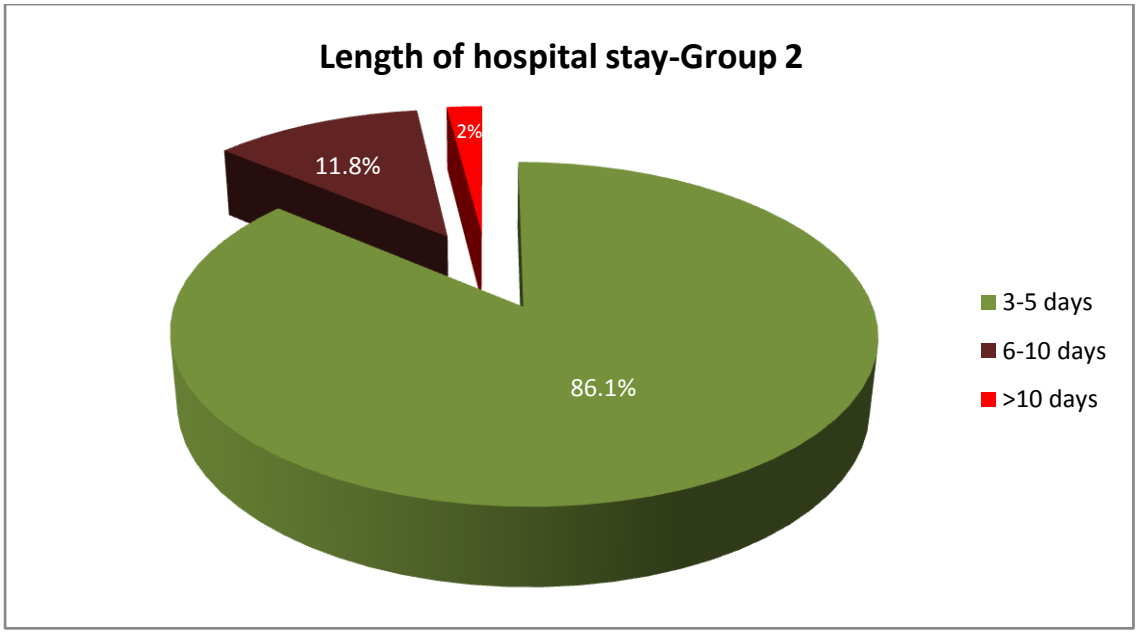
The overall incidence of UTI in the study population was 7(13.2%) . In group 1 there were 5(38.5%) and2(5%) in group 2. The incidence of UTI in group 2 appeared to be less when compared to group 1, even though it was not statistically significant.

Table 16: Length of the hospital stay

Length of hospital s	Group 1	Group 2	P value
3-5 days	272(90.1%)	255(86.1%)	0.139
6-10 days	28(9.3%)	35(11.8%)	
>10 days	2(0.7%)	6(2.0%)	

Figure9 : Length of hospital stay





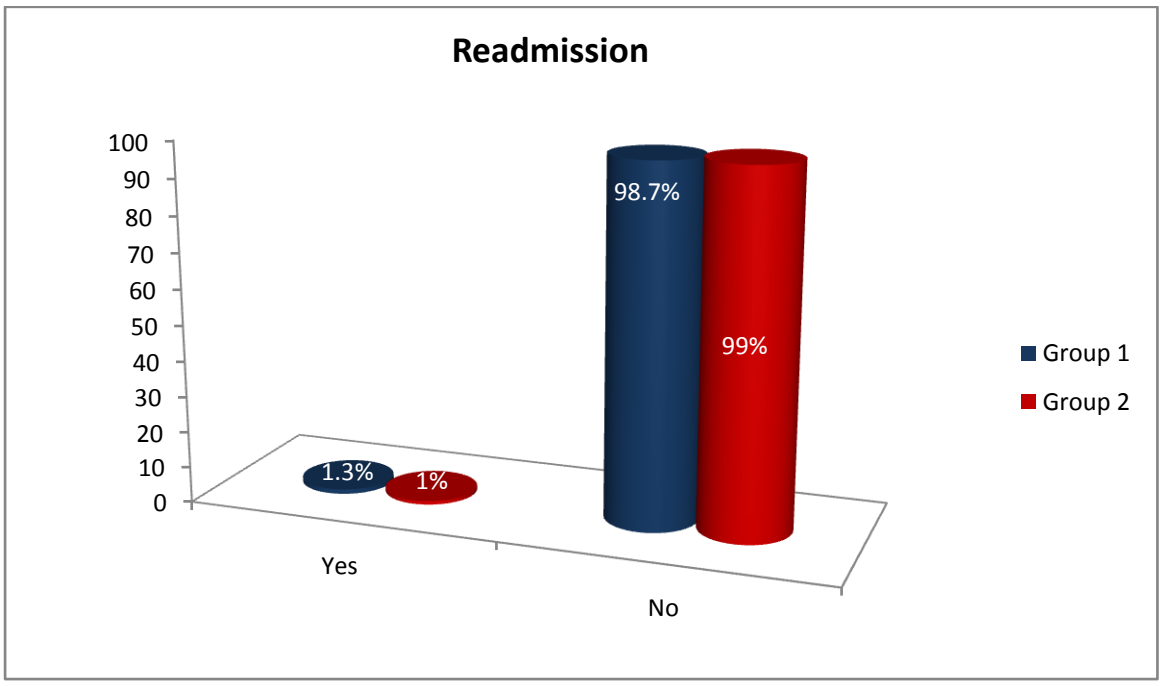
In the present study, the duration of hospital stay was analysed , as 3 categories. There were 272(90.1%) in group 1 and 255(86%)in group 2, whose hospital stay lasted from 3-5 days, which was considered as normal following CD. There were 28(9.3%)in group 1 and 35(11.8%)in group 2 who had a hospital stay from 6-10 days. There were 2(0.7%) women in group 1 and 6(2.0%) in group 2 who stayed in the hospital for more than 10 days. But these results were not statistically significant. The analysis revealed a trend towards lesser hospital stay in the > 3-5 days categories, though not statistically significant.

Secondary outcomes:

Table 17:Rate of readmission

Readmission	Group 1	Group 2	Total	P value
Yes	4(1.3%)	3(1.0%)	7(1.2%)	1.000
No	296(98.7%)	291(99.0%)	587(98.8%)	

Figure10 : Rate of readmission



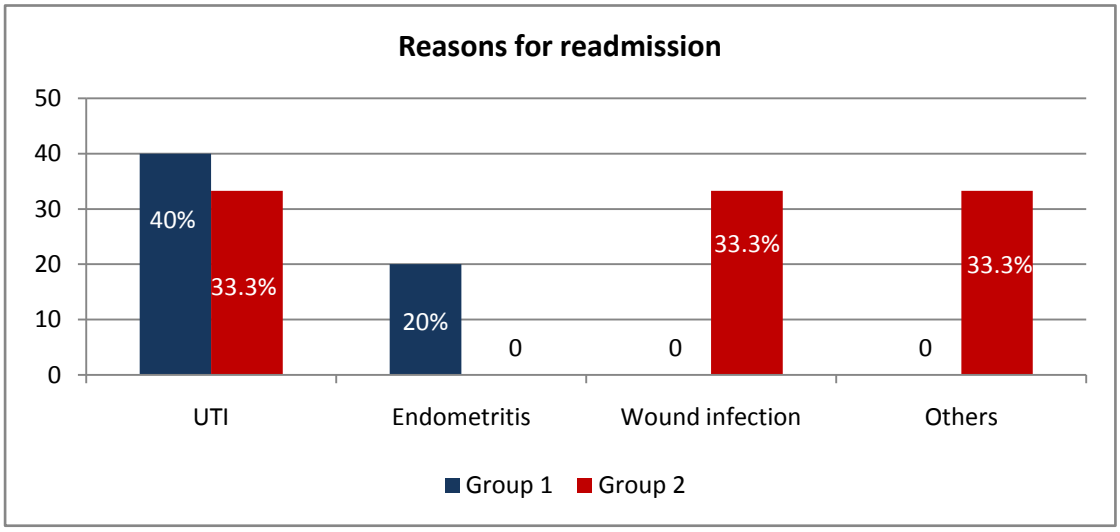
The rate of readmission into CMCH was low.There were totally only 7 women who required readmission,4(1.3%) from group 1 and 3(1%) from group 2.

Indication for readmission

Table18 : Indication for readmission

Indication for readmission	Group 1	Group 2	Total	P value
UTI	2(40.0%)	1(33.2%)	3(37.5%)	0.554
Endometritis	1(20.0%)	0	1(12.5%)	
Wound infection	0	1(33.2%)	1(12.5%)	
Others	0	1(33.2%)	1(12.5%)	

Figure11: Reason for readmission



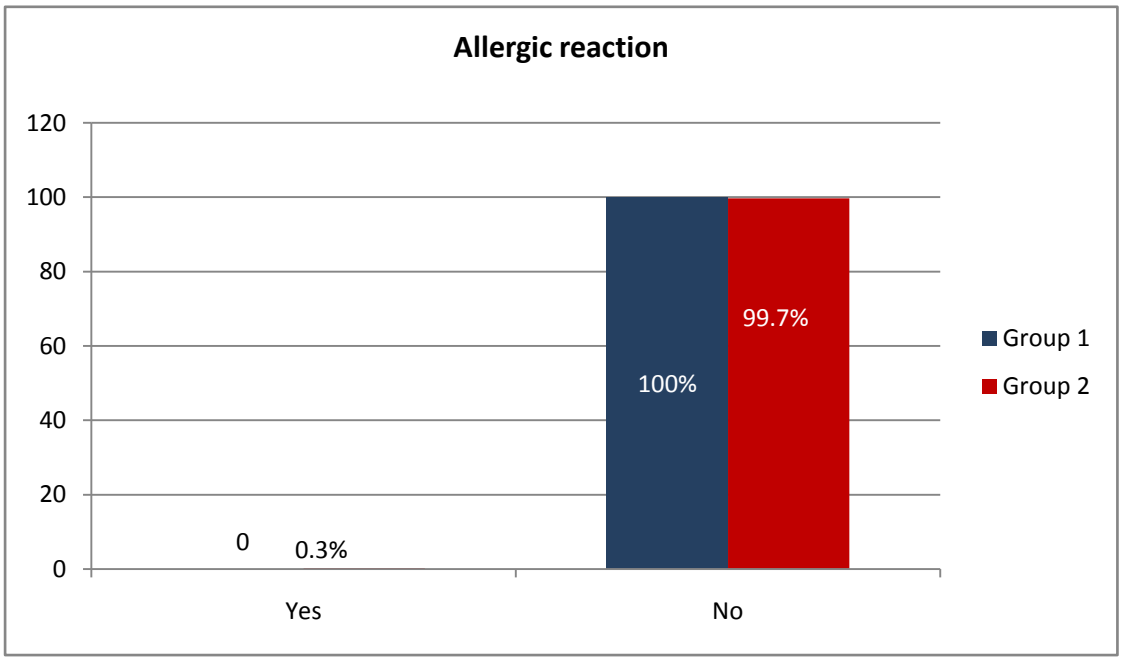
The indications for readmission were analysed in the study population, there were,3(37.5%) patients got readmitted for UTI,2 (40%) in group 1 and 1(33.3%) group 2. There was 1(20%) patient group 1 who was readmitted for endometritis. There was 1(33.3%) in group 2 who was readmitted for SSI and 1(33.3%) with breast abscess in group 2(others category).

Allergic reaction to the study antibiotics:

Table 19: Allergic reaction to the study drug

Allergic reaction	Group 1	Group 2	Total	P value
Yes	0	1(0.3%)	1	1.000
No	302	295(99.7%)	597	

Figure 12: Allergic reaction to the drugs:



In the study there was 1(0.3%) patient with probable allergic reaction in group 2.No allergic reactions were noted in group 1 . This was not found to be significant.

Multivariate analysis of the primary outcome

Table 13: Surgical site infection

Variables	Intervention		P value
	Extended Spectrum (n=11)	Narrow Spectrum (n=16)	
Administration of antibiotics			
15 – 30 min	4 (36.4)	7 (63.6)	
30 – 1 Hr	4 (44.4)	5 (55.6)	
>1 Hrs	3 (42.9)	4 (57.1)	0.927
Gravidity			
Primigravidae	3 (21.4)	11 (78.6)	
Multigravidae	8 (61.5)	5 (38.5)	0.034
Antenatal risk factors			
HTN	-	1 (100.0)	
GDM	2 (50.0)	2 (50.0)	
Hypothyroid	-	1 (100.0)	0.472
Preoperative haemoglobin			
>11gm (%)	10 (40.0)	15 (60.0)	
7 – 10gm (%)	1 (50.0)	1 (50.0)	1.000
<7 gm (%)			
BMI			
<18.5 Kg/m^2	-	-	
18.5 – 24.9 Kg/m^2	4 (44.4)	5 (55.6)	
25 – 29.9 Kg/m^2	3 (27.3)	8 (72.7)	
>30 Kg/m^2	3 (60.0)	2 (40.0)	0.438
Duration of PROM			
<6 Hrs	1 (50.0)	1 (50.0)	
6 – 12 Hrs	3 (42.9)	4 (57.1)	
13 – 18 Hrs	2 (40.0)	3 (60.0)	0.971
>24 Hrs	-	-	
Type of Cesarian delivery			
Elective	5 (55.6)	4 (44.4)	0.320
Emergency	6 (40.0)	11 (64.7)	
Blood Loss			
<500 ml	9 (37.5)	15 (62.5)	
600 – 1000 ml	2 (66.7)	1 (33.3)	0.549
1100 – 2000 ml	-	-	
Length of hospital stay			
3 – 5 days	10 (47.6)	11 (52.4)	
6 – 10 days	1 (20.0)	4 (80.0)	
>10 days	-	1 (100.0)	0.370

Table 13:Endometritis

Variables	Intervention		P value
	Extended Spectrum (n=5)	**Narrow Spectrum (n=17)**	
Administration of antibiotics			
15 – 30 min	-	5 (100.0)	
30 – 1 Hr	4 (40.0)	6 (60.0)	
>1 Hrs	1 (14.3)	6 (85.7)	0.178
Gravidity			
Primigravidae	1 (11.1)	8 (88.9)	
Multigravidae	4 (30.8)	9 (69.2)	0.360
Antenatal risk factors			
HTN	1 (50.0)	1 (50.0)	
GDM	1 (33.3)	2 (66.7)	
Hypothyroid	-	1 (100.0)	
Others	1 (50.0)	1 (50.0)	0.828
Preoperative haemoglobin			
>11gm (%)	5 (23.8)	16 76.2)	
7 – 10gm (%)	-	1 (100.0)	1.000
<7 gm (%)	-	-	
BMI			
<18.5 Kg/m^2	-	1 (100.0)	
18.5 – 24.9 Kg/m^2	-	6 (100.0)	
25 – 29.9 Kg/m^2	4 (50.0)	4 (50.0)	
>30 Kg/m^2	1 (16.7)	5 (83.3)	0.146
Duration of PROM			
<6 Hrs	1 (50.0)	1 (50.0)	
6 – 12 Hrs	-	3 (100.0)	
13 – 18 Hrs	2 (50.0)	2 (50.0)	
>24 Hrs	-	2 (100.0)	0.329
Type of Cesarian delivery			
Elective	1 (12.5)	7 (87.5)	0.387
Emergency	4 (28.6)	10(71.4)	
Blood Loss			
<500 ml	2 (16.7)	10(83.3)	
600 – 1000 ml	3 (30.0)	7 (70.0)	0.624
1100 – 2000 ml	-	-	
Length of hospital stay			
3 – 5 days	3 (42.9)	4 (57.1)	
6 – 10 days	2 (16.7)	10 (83.3)	
>10 days	-	3 (100.0)	0.253

Table 14:Urinary tract infection:

Variables	Intervention		P value
	Extended Spectrum (n=5)	Narrow Spectrum (n=2)	
Administration of antibiotics			
15 – 30 min	-	1 (100.0)	
30 – 1 Hr	3 (100.0)	-	
>1 Hrs	2 (66.7)	1 (33.3)	0.155
Gravidity			
Primigravidae	2 (66.7)	1 (33.3)	
Multigravidae	3 (75.0)	1 (25.0)	1.000
Antenatal risk factors			
HTN	-	-	
GDM	2 (100.0)	-	
Hypothyroid	-	-	
Others	-	-	-
Preoperative haemoglobin			
>11gm (%)	5 (71.4)	2 (28.6)	
7 – 10gm (%)	-	-	
<7 gm (%)	-	-	-
BMI			
<18.5 Kg/m^2	-	-	
18.5 – 24.9 Kg/m^2	3 (100.0)	-	
25 – 29.9 Kg/m^2	2 (100.0)	-	
>30 Kg/m^2	-	2 (100.0)	0.030
Duration of PROM			
<6 Hrs	-	-	
6 – 12 Hrs	1 (100.0)	-	
13 – 18 Hrs	1 (50.0)	1 (50.0)	
>24 Hrs	-	-	1.000
Type of Cesarian Section			
Elective	3 (75.0)	1 (25.0)	
Emergency	2 (66.7)	1 (33.3)	0.809
Blood Loss			
<500 ml	4 (80.0)	1 (20.0)	
600 – 1000 ml	1 (50.0)	1 (50.0)	1.000
1100 – 2000 ml	-	-	
Length of hospital stay			
3 – 5 days	3 (75.0)	1 (25.0)	
6 – 10 days	2 (66.7)	1 (33.3)	1.000
>10 days	-	-	

Table 15: Cross analysis on length of hospital stay for 6-10days and >10 days

Variables	Yes	No	P value
Endometrtis	15(68.2%)	55(9.6%)	0.000
Surgical site infections	6(22.2%)	60(10.7%)	0.063
UTI	3(42.9%)	68(11.5%)	0.011

DISCUSSION

In this study, which was done to compare the effect of adding extended spectrum antibiotics to the regular narrow spectrum antibiotics as prophylaxis at CD, the sample size of 1998 could not be completed within the time frame. The enrollment was stopped on July 30th for analysis.

According to Lomas et al, without antibiotic prophylaxis ,the rate of endometritis was reported as 20-85% and the rate of SSI was 25%(100).In the Cochrane review 2014,the review found that there was 60% reduction in endometritis and SSI ,70% reduction in serious maternal infectious complication when prophylactic antibiotic was given compared with placebo(6).According to the ACOG,NICE guidelines, WHO,SOGC and the Swedish society of Obstetrics and Gynaecology, the recommendation was that first generation cephalosporins be used as prophylaxis and that it should be administered 60 minutes prior to skin incision , the dose to be doubled if the patient was obese(7,92,101). Where narrow spectrum antibiotic (Inj.Cefazolin) was used, the rate of endometritis was found to be 23%. When extended spectrum antibiotic (Inj.Azithromycin) was added to the narrow spectrum as prophylaxis, the rate of endometritis was decreased to 2.3%. In the studies done by O'leary, Pitt et al, Meyer et al,Andrews et al , with the addition of extended spectrum antibiotic (eg. Azithromycin, Metronidazole, Gentamycin), there was a significant 30 to 60% reduction in post CD infectious morbidity , a decrease in the length of hospital stay and the cost with the use.(103)

In the study by Tita et al, in the year2008,it was found that there was a significant reduction in endometrtis, SSI, urinary tract infection and length of hospital stay after adding extended spectrum antibiotic(Azithromycin) as prophylaxis at CD(102–104).In another cohort study done by Tita et al ,done over 3 consecutive time periods ,with the addition of Inj.Azithromycin or oral Azithromycin to Inj. Cefazolin as prophylaxis, it resulted in a significant reduction in wound infection($P<0.02$) and endometritis($P<0.001$).

There have been no studies comparing the outcomes when extended spectrum antibiotic was used along with narrow spectrum antibiotic in an RCT.

In the present study, which compared the addition of extended spectrum antibiotic Inj.Azithromycin to Inj.Cefazolin, with In. Cefazolin alone, the main infectious morbidity , represented by the primary outcomes of endometritis ,SSI ,and UTI were found to have reduced from 5.8% ,5.5% ,5% respectively with narrow spectrum antibiotic to 3.7%, 4.6% and 38.5.0% respectively, with extended spectrum antibiotics. This was not found to be statistically significant.

When the outcome of endometritis alone was considered, it was found that there were a total of 3.7% women with evidence of endometriosis. In the group who had extended spectrum Azithromycin (group 1) there were 1.7%, as compared to the narrow spectrum group (group 2), which had 5.8% with endometritis.. There was statistically significant reduction (p value of 0.009) of evidence of endometritis with extended spectrum antibiotic in the univariate analysis, which was then found insignificant in the multivariate analysis. This was similar to the study done by

Andrew et al and Tita et al(56,102). But, the multivariate analysis did not reveal statistical significance in the present study. This could be due to the small sample size, and once the sample size is completed, these results could be different.

With the primary outcome of SSI, the incidence (as shown in Table 14) was 4.6% , of which group 1 had 3.7% and group 2 had 5.5%. this was not statistically significant as well, though the rate of SSI showed a trend towards lesser incidence of SSI with extended spectrum antibiotics. This finding was again similar to the study done by Andrew et al and Tita et al(56,10).

As far as UTI was considered, the incidence of urinary tract infection(UTI) (as shown in Table 15), was 5(38.5%) in group 1 and 2(5%) in group 2. The incidence of UTI in group 2 appeared to be less when compared to group 1, even though it was not statistically .Inj.Azithromycin was not protective against UTI.

When length of hospital stay was analysed, it was found that (as in Table 16)in the present study , duration of stay less than 5 days were the same in both groups, whereas it was 9.3% in group 1 and 11.8% in group 2 for those who stayed in the hospital for 6-10days. For those patients who stayed for more than 10 days, there were 0.7% in group 1 and 2% in group 2.(P-0.139). Though the number of days of hospital stay seemed to be longer in group 2, these results were again not statistically significant.

The rate of readmission into the same institution, which was an indirect marker for infectious morbidity in the long run, (as shown in Table 17), was very low. There were totally only 7 women who required readmission,4(1.3%) from group 1 and

3(1%) from group 2.These results were not statistically significant(P value-1.000). But, there could have been admissions or out patient visits to other Doctors or Clinics elsewhere by the patients, which could not be ascertained in this study.

There were no maternal deaths due to sepsis or other infectious morbidity in the study.

All considered, even though endometritis was significantly lower in the extended spectrum group, when multivatraite analysis was carried out, this was not found significant ,as was shown in other studies by Tita et al and Andrew et al.

Similarly, the other main infectious morbidities that were studied in the present trial, SSI and UTI, did not show any significant difference with the addition of extended spectrum antibiotic, as prophylaxis.

The reason for this insignificance, could be because the sample size was not reached, more numbers would be needed to show statistical difference.

When assessing the safety profiles of both groups, allergic reaction to the study antibiotics (as shown in Table 19) ,there was only 1 patient with probable allergic reaction in group 2.There were no allergic reactions noted in group 1 . This was not found to be significant (P value-1.000).

LIMITATION

In the Christian Medical College Hospital which is a tertiary level hospital, there were 14,276 deliveries in the year 2014. The number of CDs were 3985 and the CD rate was 29%.In spite of the large number of CDs that are performed, adequate numbers could not be included into the study, as dedicated research personnel were not available for the study for recruiting and detailed follow up.

About 25 patients were lost to follow up due to various reasons - inability to reach them due their wrong contact number given at the time of randomisation . This could have been avoided if more care was taken to get information.

Variables such as haemoglobin evaluation was not done preoperatively or in third trimester, which would have been a more accurate way of assessing the HB status of the patients .

BMI calculated did not necessarily indicate pre pregnancy or early pregnancy BMI which is a better indicator of adverse pregnancy outcomes like SSI. Many patients had their first antenatal check up in CMC in their 3rd trimester.

The other draw back was that many primary and secondary outcomes were not statistically significant because the target sample size was not reached.

CONCLUSION

1. The primary objective was to assess incidence of endometritis, SSI, UTI, and length of hospital stay . In the present study, the conclusions were the following :

   - The rate of endometritis reduction was statistically significant (p value of 0.009) with extended spectrum antibiotic in the univariate analysis, which was then found insignificant in the multivariate analysis.

   - Similarly, the incidence of SSI was significantly less in extended spectrum antibiotic, with univariate analysis, but with multivariate analysis, was not statistically significant.

   - The incidence of UTI was more in the extended spectrum antibiotics group, when compared to the narrow spectrum antibiotic group, but was not found to be statistically significant.

   - The length of hospital stay of more than 6-10 days and more than 10 days were less in the extended spectrum antibiotic group, when compared with the narrow spectrum antibiotic group, but was not found to be statistically significant.

2. There was no allergic reaction to extended spectrum antibiotic ,hence it can be concluded that it can be safely administered.

3. The rate of re admissions were more in the extended spectrum group, when compared with the narrow spectrum antibiotic group .This was not found to be statistically significant.

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ANNEXURES

Department of Obstetrics And Gynaecology

Christian Medical College, Vellore

A Double blind, randomised controlled trial comparing the effect of extended spectrum antibiotics with narrow spectrum antibiotic , for prophylaxis in Cesarean delivery.

Information sheet

You are requested to participate in a study , comparing the benefits of antibiotics administered during Caesarean delivery and their effect on the mother and baby. At present, a single dose of antibiotic (Cefazolin) is routinely administered to the mother, half an hour prior to the Caesarean, according to the international recommendations, in order to reduce uterine infections after delivery. There is recent evidence suggesting that addition of a second antibiotic (Azithromycin) will reduce the incidence of infection further. In this study, a comparison will be made between the two regimens of prophylactic antibiotics.

Cefazolin controls infection caused by limited number of organisms.

What happens if the Azithromycin is given along with Cefazolin?

Azithromycin, due to its longer duration of action, achieves higher concentrations in the tissues. In addition, transfer to the baby is less than other antibiotics commonly used for this indication.

If you take part what will you have to do?

Both groups in the study will receive the Injection Cefazolin as per routine practice. The second group will receive Inj. Azithromycin in addition. In order to blind the participants and the doctors as to what treatment is being received by the patient, those who are not receiving the second antibiotic will receive a placebo (a similar looking injection which has no antibiotic value)

The treatment that you will be receiving will be decided by a computer programme and will be revealed only at the end of the study.

You will continue to receive routine care as per the standard hospital protocols. You will be expected to come for a review to the hospital, 6 weeks after the Caesarean section ,for a routine postnatal check up. At the start of the study, in the ward and the 6 weeks postnatal visit, you will be asked questions about your wellbeing .No additional procedure or blood tests will be done for this study, unless you or your baby develop infections.

If at any time you experience fever or redness or any discharge from the surgery site or any wound gaping, you will be expected to report this to your unit doctor. In case there is need for additional information by the doctors conducting the study,they will contact you.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw from this study. If you do so, this will not affect your usual treatment at this hospital in any way .In addition, if you experience any serious side effects, you will be given appropriate treatment.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you but if you do develop any side effects or problem due to the drug or drug administered as part of the study, this will be treated free. We are unable to provide any monetary compensation, however.

Will you have to pay for the study tablets?

Cefazolin is the drug routinely used as antibiotic for the Caesarean delivery which you need to buy anyways. Inj. Azithromycin and the placebo injection will be provided from the study fund by the hospital.

What happens after the study is over?

Since these drugs are given only as a prophylactic treatment, after the study is over you will not get any further benefit other than the protection against infection you have already got from such treatment.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of the results. However, your

medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

CONSENT TO TAKE PART IN A CLINICAL TRIAL

Study Title: Prophylactic antibiotics in Caesarean section(PACS-study)

Study Number:

Participants' name:

Date of Birth/Age (in years):

I_____

_____, daughter/wife of_____

(Please tick boxes)

Declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. [ ]

I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]

I also understand that neither I, nor my doctors, will have any choice or knowledge of what drug is being administered. [ ]

I understand that I will receive free treatment for any study related injury or adverse event but I will not receive other financial compensation [ ]

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]

I understand that my identity will not be revealed in any information released to third parties or published

I voluntarily agree to take part in this study.

Name:

Signature or thumb print:

Date:

Name of witness :

Signature or thumb print :

Relation to participant :

Date:

Signature of the Investigator :

Date :

Study Investigator ‘s Name :

Profoma Sheet

1.Name: Age: Hospital no: Date:

Address : Gestational Age: Ph No:

2.Serial no:

3.Time of starting antibiotics:

4.No: of cefazolin dose:**1**.1 **2**.2 **3**.>2

5.Indication for additional dose of cefazolin: **1**.Increased duration of sugery **2**.Morbid obesity

6.Time of skin incision :

7.Gravidity - **1**.Primigravida **2**.Multigravida

8.Antenatal risk factors: **1**.HTN **2**.DM **3**. Hypothyroid **4**.Others

9.Preoperative Hemoglobin: **1**.>11gm% **2**.7-10.9gm% **3**.<7gm%

10.BMI: **1**.<18.5kg/m2 **2**. 18.5-24.9kg/m2 **3**.25-29.9kg/m2 **4**.>30kg/m2 **5**.>40kg/m2

11. Duraation of PROM: 1.<6hrs 2.6-12hrs 3.13-18hrs

12. Type of Cesarean section: **1**.Elective **2**.Emergency **3**.Semi emergency

13.Indication forEmergency cesarean section: **1**.NRFS **2**.Abnormal lie in labor **3**.Prev LSCS with NRFS **4**.IUGR **5**.Labor dystocia **5**.Failed Induction **6**.Others.

14 Indication for Semi emergency section: **1**.Previous LSCS not willing for VBAC in Labor **2**.Posted for elective LSCS comes in labor 3.others

15. Indication for Elective caesarean section: **1**.Previous LSCS not willing for VBAC **2**.Breech presentation **3**.Twins with first twin non vertex **4**.IUGR with abnormal dopplers 5.others

16. Duration of Surgery: **1**.1hr **2**.1-2hrs **3**.>2hrs

17. Blood Loss: **1**.<500ml **2**.600-1000ml **3**.1100-2000ml

18. Intraoperative Complication: **1**.PPH **2**.Bladder injury 3.Extension of uterine incision

19. Blood Transfusion: **1**.Yes **2**.No

20.No: of Blood transfused: **1**.1-2 **2**.3-4 **3**.>5

21.No: of Blood products transfused:

Postoperative monitoring in the Ward

1. No: of days of hospital stay:

2.Evidence of Endometritis(Temp->100.4F or uterine tenderness or foul smelling Lochia) : **1**.Yes **2**.No

3.Febrile Morbidity(100.4F in 2 occasion 6 hrs apart without cause):**1**.Yes **2**.No

4.Surgical site infection:**1**.Yes **2**.No

5.Need for therapeutic antibiotics: **1**.Yes **2**.No

6.Indication for therapeutic antibiotics: **1**.UTI **2**.Endometritis **3**.Surgical site infection 4.others

7.Allergic reaction to study drugs: **1**.Yes **2**.No

Discharge to 42days of postpartum:

1.Readmission : **1**.Yes **2**.No

2.Need for antibiotics: **1**.Yes **2**.No

3.Number of hospital visit from the time of discharge to 42days postpartum: **1**.Nil **2**.1-2 **3**.2-3

4.Reason for Readmission: **1**.UTI **2**.Endometriti **3**.baby‘s sake 4.surgical site infection **5**.others

5.Length of hospital stay : **1**.2-3days **2**.4-7days **3**.>7days

DATA SHEET

slno	hno	age	Ges age	date	Anti bio	gravid	Ante risk	Riskoth	Pre hemo	bmi	Dur prom	cesarean	Eme rcs	Eme roth	ieses	semioth
1	420683f	25	37	2/24/2015	1	2			1	3		3			1	
2	094784G	27	37.1	2/24/2015	1	2			1	2	2	2	5			
3	030736g	17	40.3	2/24/2015	2	1			1	4	2	2	3			
4	163496G	25	37.3	2/25/2015	2	2	2		1			1				
5	059686G	28	39.2	2/25/2015	2	2			2			1				
6	045781f	30	37.6	2/25/2015	2	2			1			1				
7	120976g	29	40	2/25/2015	2	1	2		1	3	2	2	3			
8	150008g	25	39.3	2/25/2015	2	2			1	2		3			1	
9	397323f	23	37.1	2/26/2015	1	2			1	3	3	2	4			
10	917600f	20	39.1	2/25/2015	2	2			1	3	2	2	1			
11	598638d	26	40.4	2/26/2015	1	2			1		2	2	4			
12	169927f	20	39.1	3/2/2015	1	2			2	3	2	2	1			
13	100328f	26	40	3/2/2015	2	2			2	3		3			1	
14	032987g	27	38.4	3/2/2015	2	1	2		1	3		3			2	
15	296139f	32	39.1	3/2/2015	2	2			1	2		3			1	
16	096827f	27	40.6	2/26/2015	2	1	1		1	4	2	2	4			
17	805149d	25	35.6	2/26/2015						1						
18	5841136	29	38.3	2/27/2015	2	2	2		1	4		3			1	
19	161792g	24	38.3	2/28/2015	2	1			1	2	1	3			2	
20	667167c			2/8/2015						4						
21	117391g	22	41.1	2/28/2015	2	2			1	4	2	2	4			
22	161631g	36	40.1	3/1/2015	1	1			1	3	2	2	1			
23	381742d	36	37.5	3/1/2015	2	1	4		1	4	2	2	4			
24	049612g	29	40.3	3/1/2015	1	1			1	3	2	2	1			
25	023158g	25	40.4	3/2/2015	1	1			1	2	3	2	1			
26	133355g	17	39.4	3/2/2015	2	1			1	3	1	1				
27	016795g	30	40.4	3/2/2015	2	1			1	3	2	2	2			
28	042351g	29	38.2	3/2/2015	3	2			2	3		2	5			
29	318656d	31	38.6	3/3/2015	2	2	2		1		1	1				
30	090257g	32	40.4	3/3/2015	2	2			1	3	2	1	1			
31	020213g	23	37.2	3/3/2015	2	1	1			3		2	2			
32	613108f	30	38.5	3/5/2015	2	2			1	4	3	2	3			
33	719054f	25	37.2	3/3/2015	2	2	2		1	2	1	2	1			
34	156406f	26	38.5	3/4/2015	2	2			1	4		1				
35	096577g	26	38	3/4/2015		2			2			1				
36	454471f	30	38.3	3/4/2015	2	2			1	2		1				
37	074188g	30	37.2	3/4/2015	2	2			1	2		1				
38	188564f	24	37.4	3/4/2015	1	2			2	1		1				
39	018159f	24	38	3/4/2015	3	2			1			1				
40	870562d	24	38.5	3/4/2015	3	2			2			1				
41	004983g	20	39.5	3/5/2015	1	1			1	4	3	2	4			
42	485632f	30	38.4	3/5/2015	2	2			1	4		3			2	
43	835759f	19	39.2	3/8/2015	2	1			1	3		2	2			
44	154474g	20	39.1	3/8/2015	2	1	3		1	2		2	1			
45	927068d	33	37.4	3/10/2015	1	1	2		1	3	2	2	4			
46	938971f	25	40.4	3/6/2015	2	1			1	4	3	2	4			
47	392970f	23	39.6	3/6/2015	2	2			2	3	3	2	4			
48	017169f	26	39.3	3/6/2015	2	2			2	3	2	2	1			
49	317509f	27	40.3	3/6/2015	2	2			1	4	1	2	5			
50	021431g	21	38.5	3/6/2015	3	1			2	2		1				
51	061317g	27	39.1	3/6/2015	2	1	4		1	4	1	2	1			
52	045510g	25	40.5	3/6/2015	2	1			1	3	3	2	3			
53	451668f	36	38.3	3/7/2015	1	2			1	4	2	2	1			
54	026766g	33	39.2	3/7/2015	1	1	2		1	4	2	2	1			
55	086006g	23	37.3	3/7/2015	2	2			1	2		3			1	
56	671761d	24	38.1	3/9/2015	3	2			2	4		1				
57	071448g	24	38.1	3/9/2015	3	2	1		1	4		1				
58	194809f	22	40.6	3/9/2015	1	2			1	4		3			2	
59	136169g	25	37.1	3/9/2015	2	2			1	3		3			3	
60	938987f	29	40.5	3/9/2015	2	1			1	2	2	2	3			
61	938993f	21	37.2	3/10/2015	2	1	1		2	4	2	2	5			

62	174792g	20	38.5	3/10/2015	2	1			1		2	2	1			
63	065860g	36	38.1	3/12/2015	3	1	3		1	4		3			1	
64	566799d	33	39.4	3/9/2015	2	2			1	3	2	3			1	
65	507747a	29	37.6	3/10/2015	1	2	2		1	2	1	2	1			
66	365474d	28	39	3/10/2015	3	2			1	3		1				
67	664597d	35	38	3/11/2015	3	2	2		1	3		3			1	
68	038763f	31	38.3	3/11/2015	3	2			2	2		1				
69	167083f	27	38.3	3/11/2015	3	2			1	4		1				
70	365643f	26	38.6	3/11/2015	3	2			1	3	1	1			1	
71	211863f	28	38.2	3/11/2015	3	2			1	2		1				
72	066896f	23	37.1	3/13/2015	3	2			1	4		1				
73	439464f	25	39.5	3/11/2015	1	1			1	2	2	2	1			
74	928636f	21	37.2	3/11/2015	1	1			1		3	2	1			
75	393461F	28	40	3/13/2015	2	2			1	3	3	2	3			
76	138820G	23	39	3/12/2015	1	1			1	4	2	2	1			
77	497652d	30	37.2	3/21/2015	3	2			1	3		1				
78	112160g	27	40	3/12/2015	2	1	3		1	4	3	2	4			
79	168791g	25	39.4	3/12/2015	2	1			1	3	2	2	4			
80	602501d	31	37.5	3/12/2015	2	1	4		1	4		3			2	
81	614178d	30	38.1	3/12/2015	3	2	2		1	4		1				
82	100053g	31	38.2	3/12/2015	2	2			1	2		1				
83	040567g	28	37	3/13/2015	2	1	1		1	4	2	2	4			
84	158983g	26	39	3/13/2015	1	1	4		1	3	2	2	1			
85	068587g	24	39	3/13/2015	2	1	4		1	3	2	2	3			
86	175726g	25	39	3/14/2015	1	1			1	2	3	2	1			
87	128457g	23	37.5	3/13/2015	1	1			1	3	1	2	1			
88	504877f	32	38.2	3/14/2015	3	2	1		1	2		1				
89	232859f	23	38	3/14/2015	3	2			1	3		1				
90	143024g	29	39	3/14/2015	2	2	2		1	4		2			1	
91	940434f	24	39.1	3/16/2015	2	2	4		2	2		3	1			
92	024013g	29	39.1	3/16/2015	1	1	2		1	3	1	2	1			
93	015243g	28	41	3/17/2015	2	2			1	2	2	2	4			
94	940433f	25	40.4	3/17/2015	2	1			2	3	3	2	4			
95	940447f	25	37.5	3/19/2015	1	2	1		2	4	2	2	1			
96	680771f	28	37.2	3/19/2015	2	1	1		1	4		2			2	
97	940446f	20	37.6	3/19/2015	2	1	1		1		3	2	4			
98	717750f	31	39.5	3/22/2015	2	2			1	2		2	5			
99	175293g	31	38.1	3/25/2015	2	2	4		1	4		1				
100	084079g	19	40.4	3/22/2015	1	1	4		1	2	2	2	1			
101	860294d	23	37.1	3/18/2015	3	2	4		2	2		1				
102	293491f	25	37.1	3/18/2015	3	2	2		2	3		1				
103	90307d	24	38.1	3/18/2015	2	2			1	3		1				
104	052716f	32	37.2	3/18/2015	3	2			1	3		1				
105	877886f	19	37	3/18/2015	3	1			1	1	1					
106	044446g	19	39.4	3/18/2015	1	1	4		1	4	2	2	1			
107	064306g	25	39	3/18/2015	1	1			1	3	3	2	1			
108	168506g	24	39	3/18/2015	1	1			1	3	2	2	1			
109	940442f	28	40.3	3/18/2015	1	1			1	4	2	2	1			
110	536668d	27	39.2	3/18/2015	1	2	1		1	3	2	2	1			
111	056025g	33	37.3	3/19/2015	2	2	1		1	4		3			1	
112	085328g	24	38.5	3/20/2015	1	1			1	3	1	2	1			
113	043230g	31	39.2	3/20/2015	1	1			1	2	1	2	1			
114	079991g	26	37.3	3/20/2015	2	2	1		2	1	2	2	3			
115	082420g	21	38.4	3/20/2015	1	1			1	3	1	2	1			
116	111444g	19	37.6	3/21/2015	1	1	1		1	4	1	2	1			
117	165169g	22	38.1	3/21/2015	1	1			1	3	1	2	1			
118	116626g	29	40.3	3/21/2015	2	1			1	3	3	2	4			
119	077391g	25	37.6	3/20/2015	2	1	4		2	4		2	4			
120	546074d	26	39.1	3/21/2015	3	2	2		1	4		1				
121	161432g	32	39.1	3/24/2015	3	2			1	4		1				
122	160324g	23	40.1	3/24/2015	1	2	4		1	3	1	2	1			
123	073152g	24	38.4	3/24/2015	1	1	1		2	4	3	2	1			
124	149697g	33	40.3	3/23/2015	2	1	2		1	3		2	4			
125	043148g	31	39.6	3/26/2015	1	1			1	4	2	2	1			
126	058065g	31	39.6	3/24/2015	1	1	2		2	4	3	2	1			
127		23														
128	131471g	25	37.5	3/24/2015	1	1	1		1	4	2	2	1			

129	119589g	25	39.5	6/5/2015												
130	124755g	33	38.5	3/24/2015	1	1	2		1	4	2	2	1			
131	323093f	18	40.3	3/25/2015	3	2			1	2		1				
132	101403g	29	38.6	3/25/2015	3	1	4		2	3		1				
133	117070g	20	39.5	3/25/2015	2	1			1	2	3	2	4			
134	088440g	28	39.4	3/25/2015	3	1			1	3		1				
135	178303g	24	38.2	3/25/2015	3	1	4		2	2		1				
136	239112f	25	37.6	3/25/2015	3	2			1	2		1				
137	932508b	38	38.5	3/25/2015	2	1	1		1	3	2	2	4			
138		26	39													
139	089688g	29	38.6	3/25/2015	2	2			2	3		2	2			
140	126792g	31	40.2	3/25/2015	1	2	2		1	3	2	2	1			
141	074556g	25	39.3	3/25/2015	2	2			1	2	3	2	4			
142	174778g	25	40.2	3/25/2015	2	1			1	2	3	2	1			
143	116489g	26	40.3	3/25/2015	1	1			1	3	3	2	1			
144	755612f	25	37.3	3/25/2015	2	2	2		1	3		2	5			
145	201329b	30	39.5	3/26/2015	2	2			2	3		3			1	
146	207723f	30	38.3	3/26/2015	2	2			1			1				
147	110618f	27	38.6	3/26/2015	1	2	2		1	2	1	2	1			
148	375634f	22	40.1	3/26/2015	3	2			1	3		1				
149	189284g	22	40.3	3/26/2015	1	1			1	2	2		1			
150	076977d	39	38	3/26/2015	2	2	2		1	3		3			1	
151	031515g	24	38.3	3/27/2015	2	1	1		2	2	2	2	4			
152	627750f	37	38.2	3/27/2015	1	2	2		2	4		1				
153	940486f	20	35	3/26/2015												
154	073661g	25	37	3/27/2015	2	1			1	2		3			2	
155	614562c	29	39	3/27/2015	3	2	2		1	2		1				
156	175707g	25	39.2	3/27/2015	1	1			1	2	3	2	1			
157	940491f	25	40.1	3/28/2015	2	1	2	pri mary infertility	1	2	3	2	3			
158	170418g	20	40.4	3/28/2015	2	2		Rh negative	1	3	2	2	4			
159		27	38													
160	655199f	27	37.1	3/28/2015	2	1	4	twins,IVF	2	3		3			3	
161	417042f	27	37.1	4/8/2015	3	2	2		1	3		1				
162	422781c	34	40.4	3/29/2015	1	2			1	3	1	2	1			
163	898324d	30	38	3/28/2015	1	2			1	1		1				
164	802280f	22	39.2	3/29/2015	1	1			1	2	2	2	1			
165	940499f	23	38.2	3/29/2015	1	2	4	Anemia	2	2	1	1	1			
166	317015f			3/30/2015	1	2			1	3		3			1	
167	049606g	23	40.3	3/30/2015	2	2			1	2	3	2	4			
168	912606d	23	37.2	3/31/2015	2	2	4	twins	1	3	2	2	3			
169	858275c	34	38.3	3/31/2015	2	2				3	1	3			1	
170	384949f	21	39.6	3/31/2015	1	2			1	2	1	2	1			
171	572840D	35	38	4/1/2015	1	2			1	3		1				
172	466420c	27	37.1	3/31/2015	1	2	2	Chronic HTN	1	2		3				prev preterm LSCS in labor
173	879431d	31	37.2	4/1/2015	3	2	2		1	3		1				
174	073340g	28	37.2	4/8/2015	2	2	3		1	2		1				
175	141144g	26	38.6	3/31/2015	1	1	3	Morbidly obese	1	4	3	2	4			
176	549163d	27	37	4/1/2015	3	1	4	br asthma	1	2		1				placenta previa
177	374112f	24	37.6	4/1/2015	3	2	3		1	3		1				
178	623007f	23	38.5	4/1/2015	3	2			1	3		1				
179	454214d	32	38.5	4/1/2015	3	2			2	3		1				
180	040029g	24	38.5	3/31/2015	2	1	1		1	3	2	2	4			
181	024509f	33	38	4/2/2015	3	2	2		1	2		1				
182		22														
183	051982g	27	38.3	4/8/2015	3	2			2	3		1				
184	727070f	36	37.2	4/2/2015	3	1			2	2		3				IVF preg in early labor
185	129210g	41	37.5	4/8/2015	3	2	2		1	3		1				
186	834851d	28	38.6	4/3/2015	3	2			1	3	2	2	4			
187	165686g	31	40.3	4/7/2015	3	2			2	3	3				1	

188	090735g	28	37	4/8/2015	3	2	2		1	3		1				
189	067535g	32	40.3	#######	2	1	1		1	2	2	2	3			
190		30														
191	180133g	28	40.5	4/9/2015	2	1			1	2	2	2	4			
192	154146g	33	38	4/4/2015	1	2			1	3	2	2	4			
193	062350g	21	39.4	5/4/2015	2	1			1	2	2	2	3			
194	943537f	21	40.2	4/6/2015	2	1			1	2	3	2	5	Brow presentation		
195	081727f	28	38.1	4/8/2015	3	2	3		1	2		2				
196	099186g	26	40.5	4/7/2015	1	1			1	2	2	2	1			
197	075496f	23	38	4/7/2015	2	2			1	2	1	3			2	
198	922189f	27	39.3	4/7/2015	2	1	2		1	3	3	2	4			
199	031421g	26	39.2	4/7/2015	3	2			1	3		3			1	
200	452968d	29	39	4/8/2015	3	2			1	2		1				
201	191429f	28	38.1	4/8/2015	2	2			1	4		3				breech in labor
202	073889g	23	39.2	4/10/2015	2	1	1		1	4	2	2	3			
203	407074d	33	38	4/14/2015	3	2				3		1			1	
204	174366g	30	40.4	4/11/2015	2	1	3		1	3	3	2	3			
205	797821f	28	39.3	4/28/2015	1	1	2		1	4	3	1	1			
206	099125g	33	37.6	4/10/2015	1	1			1	4	2	2	1			
207	036312g	30	40.5	4/7/2015	1	1	2		1	4	3	2	1			
208	095237g	32	40.1	4/14/2015	1	1			1	4	1	2	1			
209	933173c	43	37	4/13/2015	2	2	1	1,2,3, morbid obese	1	4		1				
210	943563f	31	38.2	4/9/2015	2	2	4	asthma, morbily obese	1	4		1				
211	133246g	27	40.5	4/9/2015	2	1	2		1	4	4	2	3			
212	474630f	27	40	4/9/2015	2	1	2		1	4	3	2	4			
213	153802g	23	32	4/10/2015												
214	972875d	30	38.6	4/10/2015	3	2	2		1	4		1				
215	112637g	26	37.5	4/12/2015	2	1	3		1	3		3			2	
216	489300d	30	37	4/12/2015	2	2			1	3	1	3				breech with prom
217	074982g	23	38	4/13/2015	2	1	1		1	3	3	2	3			
218	424690f	21	40.4	4/14/2015	1	2			2	3	1	2	1			
219	401711f	23	38.6	4/14/2015	2	2			1	2		3			1	
220	176897g	24	41	4/14/2015	1	1			1	3	3	2	1			
221	174143g	28	37	4/15/2015	3	2			1	3		1				
222	928116d	29	38.4	4/15/2015	3	2			1	3		1				
223	836645c	30	39	4/15/2015	3	2			1	3		1				
224	979197d	25	38	4/15/2015	3	2			2	2		3				placenta previa
225	200080g	20	39.1	4/15/2015	1	2			1	3	3	2	1			
226	038619g	23	38.6	4/15/2015	3	2			1	3		1				
227	943587f	32	38.6	4/15/2015	2	2			1	4		1				
228	886417g	27	37.1	4/15/2015	2	2	1	gdm	1	3		1				
229	185004g	24	38.4	4/15/2015	3	2			2	2		1				
230	177988c	40	39.1	4/15/2015	3	2			1	3		1				
231	728729d	28	38	4/15/2015	3	2	2		1	3		1				
232	943590f	22	40	4/16/2015	1	1			1	2	3	2	1			
233	470661f	32	37	4/16/2015	2	1	2		2	3		3				twins with unfavourable cervix
234	144935g	27	40.1	4/15/2015	2	1			1	4	2	2	5	brow presentation		
235	121131g	29	39.1	4/15/2015	1	2	2		1	3	1	2	1			
236	323959d	29	39.3	4/17/2015	2	2	3		1	3	3	2	4			
237	364006a	31	39.5	4/15/2015	2	2	3	gdm	2	4	3	2	4			
238	170226g	29	38.4	4/17/2015	1	1			1	3	3	2	1			
239	parvina	29	40.4	4/16/2015	1	2	4		2	3	1	2	1			
240	814546d	25	39.6	4/18/2015	1	1			1	3	2	2	1			
241	yasmeen	31	38	4/21/2015	2	2			2	2	1	3			1	

242	206846g	23	37.5	4/21/2015	2	2			1	3		3			1	
243	120980g	23	40.5	4/21/2015	2	1			2	2	3	2	3			
244	230691d	31	38.1	4/27/2015	2	2			2	3		3			1	
245	889353f	28	37.2	4/28/2015	2	2	2	HTN	1	4	3	2	4			
246	331805f	25	39.1	4/22/2015	2	2	2		1	4	3	3			2	
247	488162d	25	37.2	4/22/2015	2	1	1		2	3		3				placenta praevia
248	906368f	27	38.6	4/22/2015	3	2	2		1	3		1				
249	441319f	20	39.3	4/22/2015	3	2			1	2		1				
250	132900g	28	39	4/22/2015	2	2			1	2		1				
251	699900d	23	39	4/22/2015	3	2			1	2		1				
252	051127g	32	39.1	4/22/2015	3	2	2		1	2		1				
253	128338g	27	37.4	4/23/2015	2	1			1	2		3			2	
254	469587f	20	37.2	4/23/2015	3	2			1	2		1				
255	301423f	27	37.2	4/22/2015	2	2			1	2		3			2	
256	081193g	25	39.2	4/23/2015	2	2	1		1	4		1				
257	951221f	28	40.4	4/22/2015	2	1			1	3		2	3			
258	180604g	28	39.6	4/24/2015	1	2	2		1	4	2	2	1			
259	593491a	28	39.6	4/24/2015	2	1			1	3	3	2	3			
260	173092g	22	39.1	4/23/2015	1	1			1	3	1	2	1			
261	926158f	26	37.4	4/24/2015	1	1			1	2	1	2	1			
262	051707g	28	41	4/24/2015	2	1			1	3	2	2	3			
263	951244f	22	37.2	4/25/2015	1	1	1		2	3		2	1			
264	422750d	33	37	4/24/2015	3	2	2		1	3		1				
265	208655g	29	39.6	4/24/2015	2	1			2	3		2	3			
266	572890d	33	38	4/24/2015	3	2	2		1	3		1				
267	185443g	27	39.3													
268	349487f	24	38	4/29/2015	3	2			1	4		1				
269	104899g	21	40.4	4/29/2015	3	2			1	3		1				
270	669138d	25	38	5/3/2015	2	2			1	3		1				
271	294932f	22	38.4	4/29/2015	2	2			1	2	2	2	4			
272	379009f	26	39.4	4/26/2015	3	2			1	3		1				
273	089590f	34	39.3	4/28/2015	3	2	2		1	2		1				
274	207897g	26	40	4/28/2015	1	2	2		1	3	2	2	1			
275		24														
276	061747f	24	39.3	5/3/2015	2	2			1	3		1				
277	126523g	31	38.1	4/28/2015	3	2	2		1	3		1				
278	244922f	24	38.2	4/29/2015	3	2			1	3	1	3			1	
279	103921G	25	39.3	4/29/2015	3	2			1	3		1				
280	104684g	24	38.3	4/29/2015	2	1			1	4	3	2	4			
281	183883g	28	37.4	5/2/2015	2	1			1	3	3	2	3			
282	752913f	27	38.2	4/29/2015	2	2	1		1	3	3	2	4			
283	410919d	29	39.2	4/29/2015	3	2	2		1	3		3			3	
284	635955d	31	40.5	4/29/2015	2	2			1	2	1	3			1	
285	732061d	27	39	4/29/2015	3	2			3	2		1				
286	136343f	25	37.6	4/30/2015	3	2			2	3		1				
287	982863d	29	39.2	4/29/2015	3	2			2	3		1				
288	211546g	28	38.1	4/30/2015	3	2			1	2		1				
289	743359c	36	39	5/1/2015	3	2			1	3		1				
290	087889g	26	37.6	4/30/2015	2	1			1	4	3	2	3			
291	150294g	27	39	4/29/2015	2	2			2	3	3	2	4			
292	951851f	33	40.1	5/13/2015	3	2			1	3		1				
293	482932f	28	40	5/16/2015	2	2	2		1	4	2	2	4			
294		8														
295	125030g	28	37.4	5/13/2015	3	1	1		1	1		1				
296	100679g	30	39.6	5/5/2015	1	2			2	2	1	2	1			
297	194927g	21	39.6	5/5/2015	1	2			1	3	2	2	1			
298	096251g	25	39.1	5/5/2015	3	2	2		1	2		1				
299	726239f	28	40.3	5/5/2015	1	1			1	2	2	1	1			
300	138279g	24	37.3	5/4/2015	2	1			1	2	1	3			2	
301	452598f	29	39	5/6/2015	3	2			1	3		1				
302	721233f	21	39	5/6/2015	3	2			1	1		1				
303	639310f	25	39.2	5/6/2015	3	2			1	1		1				
304	911008d	35	39.2	5/6/2015	3	2			1	4		1				
305	274340f	23	38.3	5/5/2015	3	2			1	3		1				
306	208011g	20	37.1	5/12/2015	3	1			1	3		1				
307	101611g	25	40.2	5/7/2015	2	1	1		1	2	1	3			1	

308																
309	899648d	28	40.5	5/13/2015	2	2			1	2	2	2	4			
310	951881f	26	40.3	5/18/2015	2	2			1	3		3			1	
311	869475c	30	37.5	5/6/2015	2	2			1	3		2	2			
312																
313	102660g	36	39.2	5/6/2015	1	1	1	gdm	1	2	2	2	3			
314	202105b	29	39.5	5/7/2015	1	1	2		1	2	2	2	1			
315	132023g	25	40	5/6/2015	1	2	2		1	3	2	2	1			
316	951822f	24	37.1	5/7/2015	2	2			1	4		3			1	
317	678045f	26	37.1	5/8/2015	2	2	1		1	4		2	5	spe with unfav cx		
318	138533g			5/12/2015	2	1			1	3	2	2	3			
319	049079g	21		5/7/2015	1	2			1	2	2	2	1			
320	512530f	19	38	5/7/2015	1	1	1		1	4	1	2	1			
321	074792g	26	37	5/8/2015	3	2			2	2		1				
322	062299g	20	38	5/9/2015	1	1			1	3	2	2	1			
323	173715g	27	39	5/9/2015	3	1			1	3		1				
324	130283g	28	40.4	5/9/2015	2	1	2		1	3	3	2	4			
325	446951f	27	38.3	5/15/2015	2	1			1	2		3			3	
326	183194g	29	37.2	5/11/2015	1	2	2		1	3	2	2	1			
327	848752c	28	38.4	5/14/2015	1	2	2		1	3	1	2	1			
328	126506g	28	39	5/11/2015	2	2	4		1	4	1	3			1	
329	669750f	35	39.2	5/14/2015	3	2	4		1	3		1				
330	951854f	38	37.3	5/14/2015	2	1	1		1	4		3			3	
331	221580g	25	39.4	5/11/2015	3	2	4		1	2		1				
332	352893d	35	37.4	5/13/2015	3	2	2		1	3		1				
333	261735f	37	38.1	5/12/2015	3	1			1	3		3			3	
334	833748d	35	37.4	5/11/2015	3	2	1		1	4		1				
335	065667g	26	40.6	5/12/2015	2	1			1	4	2	2	3			
336	061550g	28	38.1	5/16/2015	2	1	2		2	4	3	2	4			
337	769735f	27	40.2	5/15/2015	2	2			1	2	3	2	4			
338	189808g	28	40.4	5/16/2015	2	1			1	4	3	2	4			
339	686714f	29	40	5/15/2015	2	2	3		1	4	3	2	4			
340	207180g	33	37.5	5/16/2015	2	1	2		2	4		2	2			
341	042132f	35	37.4	5/18/2015	2	2			1	3		3			1	
342	092949g	35	37.3	5/19/2015	1	1	1		1	4	1	2	1			
343	951889f	33	39	5/19/2015	1	2			1	4	2	2	1			
344	076915g	26	40.4	5/19/2015	1	1			1	2	2	2	1			
345	2															
346	291547d	32	38.4	5/18/2015	2	2			1	2		3			1	
347	083063g	23	38.1	5/18/2015	3	2			1	3		1				
348	082648g	27	38.5	5/18/2015	2	1			2	2		1				
349	897200f	36	38	5/18/2015	3	2			1	3		1				
350	923212d	31	38.3	5/19/2015	2	2			1	3	2	2	4			
351	163351g	33	40	5/19/2015	1	1			1	4	2	2	1			
352	725705d	27	37.4	5/19/2015	3	2			1	3		3			1	
353	190088g	21	38.1	5/25/2015	2	1	1		1	3	3	2	4			
354	646196d	27	39.1	5/28/2015	2	2			1	3		3			1	
355	084046g	21	40.4	5/21/2015	1	1			1	3	2	2	1			
356	953913f	22	41.1	5/25/2015	2	1	1		1	3	3	2	4			
357	146262g	35	39	5/25/2015	2	2	2	Hypo thyroid	1	4	3	2	4			
358	072737g	23	40.5	5/19/2015	1	1			1	3	3	2	1			
359	380092f	23	38.4	5/20/2015	2	2	2		1	3		3			1	
360	702585f	22	37	5/20/2015	3	2	2		1	3		1				
361	082924d	33	38.4	5/20/2015	3	2			2	3		1				
362	217420g	24	39.3	5/20/2015	3	2			1	3		1				
363	181425d	27	39.2	5/20/2015	3	2			1	3		1				
364	131060g	19	39.1	5/20/2015	3	1			1	2		1				
365	145355g	33	39.1	5/20/2015	3	2			1	2		1				
366																
367	139798g	34	38.5	5/20/2015	3	2	2		2	4		1				
368																
369	203685g	27	38.5	5/21/2015	3	2	2		1	4		1				
370	328914f	24	38.6	6/3/2015	3	2			1	3		1				
371	797527f	30	37.1	5/20/2015	3	1	1		1	3		1				
372	071601g	22	38.6	5/20/2015	3	2			1	3		1				
373	187888g	25	38.2	5/20/2015	3	2			2	2		1				

374	073067g	29	38.1	5/20/2015	3	2	2		2	4		1				
375	206263d	30	39.2	5/21/2015	3	2			1	2		1				
376	359325f	26	39.2	6/3/2015	3	2			2	2		1				
377	126329g	27	40.4	5/22/2015	2	1			1	3	3	2	4			
378	892856f	40	38.4	5/22/2015	3	1			2	3		1				
379	116793g	26	39.2	5/22/2015	2	1			1	3	3	2	4			
380	072638g	27	40.2	5/21/2015	2	2			1	4		3			1	
381	128937g	26	39.4	5/22/2015	1	1	4	asthmatic	1	2	2	2	1			
382	366596c	33	37.6	5/21/2015	2	2			2	3	2	3			1	
383	888103f	24	39.3	5/23/2015	2	1			1	3	3	2	4			
384	212720g	35	39	5/23/2015	1	1			1	2	2	2	1			
385	953919f	21	41	5/24/2015	1	1			2	2	3	2	1			
386	947461d	33	38.2	5/26/2015	3	1			2	2		3			3	
387	100328g	29	40.5	5/23/2015	2	1			1		4	2	4			
388	953915f	29	40.5	5/25/2015	2	1			1	3	3	2	3			
389	762236c	31	37.1	5/26/2015	2	2	1		2	3		3			1	
390	953935f	16	37.3	5/26/2015	2	1	1		1	3		3			2	
391	204554f	24	39.4	6/3/2015	3	2			1	4		1				
392	149242g	26	37.1	6/8/2015	3	1			1	2		1				
393	854919d	32	38.5	5/29/2015	2	2	2		1	3		3			1	
394	001695c	29	39.2	6/9/2015	1	1			1	2	1	2	1			
395	078333g	29	38.1	5/27/2015	3	1			1	3		1				
396	623110d	34	38	6/8/2015	3	2	1		1	3		1				
397	118419g	28	37.3	6/9/2015	1	1	2		1	3	1	2	2			
398																
399	021064f	27	37.2	5/27/2015	3	2			1	2		1				
400	768486f	35	37	5/27/2015	3	1	2		1	2		1				
401	190524f	26	39.3	5/27/2015	3	2	3		1	3		1				
402	154252g	30	39.2	5/27/2015	3	2	4	asthmatic	1	3		1				
403	323134d	28	37.1	5/27/2015	3	2			1	3		1				
404	844681d	25	41.1	5/27/2015	2	2			1	2		3			1	
405	147043f	37	39	5/27/2015	3	2			1	3		1				
406	199140g	30	38.1	5/27/2015	3	1	2	Gestational HT	1	4		1				
407	194790g	24	37.5	6/17/2015	3	2			2	3		1				
408	802448d	27	39.3	5/30/2015	1	2	2		1	3	2	2	1			
409	684530c	34	38.2	5/30/2015	1	2	2		1	3	2	2	1			
410	096166g	31	38.1	5/31/2015	2	1			1	3		3			2	
411	953983f	27	37.3	6/4/2015	2	2	1		1	3	3	2	1			
412	506283f	22	39.1	5/29/2015	2	2			1	2		3			2	
413	192109g	27	38.4	5/30/2015	2	1			1	3	2	2	2			
414	953966f	28	40.4	6/1/2015	1	1	1		1	2	1	2	1			
415	281954f	28	38.5	5/31/2015	2	2			1	3		3			1	
416	627986d	32	38	5/30/2015	3	2	3		1	3		1				
417	956644f	26	40.1	6/7/2015	2	2			1	3	3	2	3			
418	222367g	22		6/3/2015												
419	470452f	33	39.1	6/5/2015	3	2	3		1	2		1				
420	202049g	28	39.5	6/6/2015	1	1	1		1	2	2	2	1			
421	130752g	30	38.2	6/2/2015	2	2			1	3	2	2	1			
422	261744f	23	40.1	6/2/2015	3	2			1	3		1				
423	090017g	23	40	6/6/2015	1	1			1	3	1	2	1			
424	livery	22		6/2/2015												
425	057008f	31	40.4	6/4/2015	2	2			1	3	2	2	4			
426	633638c	26	39.3	6/3/2015	3	1			1	3		1				
427	262996f	39	38.1	6/3/2015	3	2	2		1	2		1				
428	007692f	27	37	6/3/2015	3	2			1	2		1				
429	192139g	35	37	6/3/2015	3	2	3	Asthma, GDM	2	4		1				
430	413499f	26	39	6/3/2015	3	2			1	2		1				
431	505554f	29	39.5	6/3/2015	3	2			2	3		1				
432	216330g	34	38.1	6/3/2015	3	2			1	4		1				
433	220435g	27	40.4	6/4/2015	1	2			1	2	1	2	1			
434	098742g	28	38.5	6/3/2015	3	1			1	2		1				
435	455217f	32	40	6/3/2015	2	2			1	3		3			1	
436	211682g	23	38.6	6/3/2015	1	1			1	1	3	2	1			
437	349671d	31	39.3	6/3/2015	3	2			1	3		1				
438	121325g	34	38.1	6/3/2015	1	1			1	2	3	2	1			
439	192641c	25	37.5	6/3/2015	3	2	3		1	2		1				

440	458320f	24	39.6	6/3/2015	3	2			1	2		1				
441	111527g	29	38.1	6/3/2015	3	2			1	2		1				
442	817863a	26	39.2	6/8/2015	3	2	2		1	3		1				
443	075147g	25	40.3	6/9/2015	1	1			1	2		2	1			
444	217833f	30	37.5	6/9/2015	3	2			1	3		1				
445	402567f	26	38.5	6/10/2015	3	2			1	3		1				
446	104114g	39	38.3	6/10/2015	3	2	2		1	2		1				
447	216894d	36	38.5	6/10/2015	3	2	2		1	2		1				
448	886816f	26	38.3	6/10/2015	3	2			1	2		1				
449	116578f	30	38.3	6/10/2015	3	2			1	3		1				
450	099070g	23	38.2	6/10/2015	3	1			1	3		1				
451																
452																
453	092851g	27	38.2	6/10/2015	3	1	4	Asthma	2	4		1				
454	123667g	40	37.4	6/10/2015	2	1			1	3		3			3	
455	122864g	35	38	6/10/2015	3	2			2	3		1				
456	841009d	24	37.1	6/10/2015	3	2			2	3		1				
457	043076f	29	37.2	6/10/2015	3	2	2		1	3		1				
458		30														
459	140163g	25	40.3	6/11/2015	3	2			1	4		1				
460	216466g	29	39.5	6/11/2015	3	2			1	3		1				
461	739432d	33	38	6/17/2015	3	2	1		1	3		1				
462	844221f	31	37	6/11/2015	1	1			2	3	3	2	1			
463	084394g	24	40	6/11/2015	2	1	2		2	2	3	2	3			
464	274120f	25	38.3	6/17/2015	3	2	2		2	3		1				
465	224514g	22	40.4	6/11/2015	1	1			1	3		2	1			
466	175986g	27	40.3	6/12/2015	2	1	2		1	3	3	2	3			
467	186846g	26	38.1	6/12/2015	3	2			2	3		1				
468	244541g	19	39.1	6/13/2015	1	1			1	1	2	2	1			
469	676746f	23	39.1	6/12/2015	2	2	2		1	4	3	2	3			
470	209724g	23	37.4	6/12/2015	3	1			1	3		1				
471	485196f	23	38	6/13/2015	3	2			1	2		1				
472	330784f	25	37	6/19/2015	3	2			1	4		1				
473	956629f	24	38.6	6/13/2015	2	1	1			1	2	2	4			
474	229974g	27	40.3	6/13/2015	2	2			2	3	3	2	4			
475	068533f	23	37.6	6/13/2015	3	2			1	4		1				
476	903742f	29	38.1	6/15/2015	3	2	3		1	4		1				
477	712537f	25	38.5	6/16/2015	3	2			1	2		1				
478	176877g	28	38.6	6/16/2015	3	2			1	3		1				
479	223696g	21	39.1	6/16/2015	1	1	2		2	3	3	2	1			
480	211093g	36	40	6/16/2015	2	2	2		1	2	3	2	4			
481	245475g	27	39.3	6/16/2015	1	1	1		1	4	2	2	1			
482	079693d	36	37	6/15/2015	3	2			1	4		1				
483	191827g	22	40.5	6/16/2015	1	1			1	4	3	2	1			
484	110009g	23	38	6/16/2015	3	2			1	3		1				
485	122786g	27	40.2	6/15/2015	1	1			1	2	3	2	1			
486	194245g	29	37.1	6/17/2015	3	2	1		1	3		1				
487	348884f	23	39.4	6/17/2015	3	2			1	2		1				
488	284547f	24	38.4	6/17/2015	3	2			1	4		1				
489	229447g	31	39.2	6/17/2015	3	2			1	4		1				
490	956644f	26	40.1	6/17/2015	2	2			1	2	3	2	3			
491	211280d	29	37.6	6/18/2015	3	2	2		1	4		1				
492	916771c	29	39.4	6/18/2015	3	2			1	2		1				
493	242011g	31	40.6	6/18/2015	2	1			1	3	3	2	3			
494	182292g	23	37.1	6/17/2015	3	1	2		2	3		1				
495	214801g	25	40.4	6/28/2015	1	1	2		1	4	3	2	1			
496	806812d	30	38	6/17/2015	3	2	2		1	3		1				
497	166281g	33	37.5	6/17/2015	2	1	3		1	3		3			2	
498	869182d	27	37.6	6/18/2015	3	2			1	2		1				
499	817120d	25	39.1	6/18/2015	3	2			2	4		1				
500	703722f	28	39.1	6/18/2015	3	2			1	2		1				
501	234103f	31	39.1	6/18/2015	3	2			1	3		1				
502		21														
503	630535d	28	38	6/20/2015	3	2	3		1	3		1				
504	108187f	24	38.1	6/20/2015	3	2			1	2		1				
505	989536d	31	38.2	6/26/2015	2	2			1	3		3			1	
506	467714d	26	37.5	6/27/2015	3	2			1	2		1				

507	040028g	29	37.3	6/27/2015	3	2	1	GDM	1	3		1				
508		22														
509	496885f	30	39.4	6/20/2015	1	2			2	4	2	2	1			
510	089494g	37	40.1	6/20/2015	1	2			2	3	1	2	1			
511	956681f	24	38.4	6/20/2015	3	2			2	2		1				
512	094519g	20	38.3	6/22/2015	3	2			1	3		1				
513	607108d	27	40.5	6/23/2016	1	2			1	4	2	2	1			
514	170731g	23	37.3	6/23/2015	3	1			2	2		1				
515		22														
516	449237c	30	38.1	6/23/2015	3	2			1	3		1				
517	155335g	24	38.1	6/24/2015	3	2			1	2		1				
518	948860f	26	39.6	6/24/2015	3	2			1	2		1				
519	018411f	29	38	6/24/2015	3	2			1	2		1				
520	406802f	26	38.4	6/24/2015	3	2			1	2		1				
521	328791f	25	39.5	6/24/2015	3	2			1	3		1				
522	896315d	26	37.6	6/24/2015	3	2			1	3		1				
523	272317b	38	37	6/24/2015	3	2			1	2		1				
524	116193g	34	39.1	6/24/2015	3	2			1	2		1				
525	144271g	36	39.5	6/24/2015	2	1	2		1	2	3	2	4			
526	250949g	31	38.1	6/24/2015	2	2			2	3	2	2	4			
527	928793f	33	39.3	6/24/2015	2	1	2		1	3	3	2	3			
528	497941f	28	40.1	7/9/2015	3	2			2	3		1				
529	838422f	30	38.1	6/24/2015	3	1			2	2		1				
530	945127d	30	37.6	6/24/2015	1	2	2		1	4	3	2	1			
531	399679f	26	38.3	6/24/2015	3	2			1	3		3			1	
532	689211c	27	40.1	6/26/2015	2	2			2	4	2	2	4			
533	150850g	30	39.2	6/26/2015	3	2	2		1	3		1				
534	308156f	25	37	6/26/2015	3	2			1	4		1				
535	786170d	31	38.5	6/26/2015	2	2			2	2		3			2	
536	230535c	33	39.6	6/26/2015	3	2			1	3		1				
537	500861f	28	39	6/27/2015	2	1	2		1	4		2	4			
538	130524g	19	38.1	7/9/2015	1	1			1	2	2	2	4			
539	210473g	27	40	6/28/2015	1	1			1	3	2	2	1			
540	237189g	25	38.5	7/9/2015	1	1			2	2	3	2	1			
541	909671f	19	38.2	6/28/2015	1	1			2	2	2	2	1			
542	025993d	31	38.3	6/30/2015	3	2	2		1	4		1				
543	134606g	29	40.3	6/29/2015	2	1			1	2	3	2	4			
544	282957f	37	37.1	6/29/2015	3	2	2		1	3		1				
545	22															
546	254935g	24	40.2	7/9/2015	1	1			1	3	3	2	1			
547	853919d	25	38.6	7/1/2015	3	2			1	2		1				
548	872981d	26	38	7/1/2015	3	2			2	2		1				
549	710576d	29	39	7/1/2015	3	2			1	4		1				
550	379075f	25	38.4	7/1/2015	3	2			1	3		1				
551	606909d	32	38	7/1/2015	3	2			1	2		1				
552	097094f	36	39.4	7/1/2015	3	2	2	Hyrpo thyroid	1	3		1				
553	217556f	25	38.3	7/1/2015	3	2			1	2		1				
554	130374f	26	40.2	7/30/2015	3	2			1	3	2	2	4			
555	556225d	33	38.2	7/1/2015	3	2	2		1	3		1				
556	059657f	30	38.1	7/1/2015	3	2			1	3		1				
557	943536f	19	38.2	7/5/2015	1	1			1	2	2	2	1			
558	243946g	21	40	7/5/2015	1	2			1	3	3	2	1			
559	408695d	28	38.3	7/6/2015	3	2			1	2		1				
560	118217g	25	37.6	7/4/2015	2	1			1	2	1	2	2			
561	156859f	33	37	7/5/2015	3	2	2		2	3		1				
562	719631d	24	38.1	7/4/2015	1	2			1	3	4	2	1			
563	007124d	33	39.2	7/4/2015	2	2	2		1	2		2	4			
564	960347f	20	41	7/4/2015	1	1			1	2	1	2	4			
565	222867g	26	38.1	7/3/2015	2	1			1	3	3	2	3			
566	225470g	24	38.4	7/2/2015	2	1	1		1	2		2	2			
567	129134g	27	39.6	7/4/2015	2	1	2		1	4	3	2	4			
568	960332f	25	39.6	7/3/2015	2	2			1	3	3	2	3			
569	983088d	30	37.3	7/3/2015	3	2			1	2		1				
570	0															
571	220257g	30	40.1	7/2/2015	1	1			1	3	2	2	1			
572	960315f	23	40.6	7/2/2015	2	1			1	3		2	4			

573	193778g	31	37.2	7/5/2015	3	1			1	2		1				
574	0															
575																
576	730853d	25	37.6	7/7/2015	1	2			2	3	2	2	1			
577	0															
578	213823g	25	39.3	7/12/2015	2	1			1	3	3	2	3			
579	142825g	23	37.6	7/7/2015	1	1	3		1	4	2	2	1			
580	706600f	35	38.2	7/7/2015	3	2	2		1	4		1				
581	0															
582		0														
583	182360g	21	39.5	7/7/2015	1	1			2	2	2	2	1			
584	192296g	22	40.5	7/8/2015	1	1			2	2	3	2	1			
585	380462f	25	38.6	7/8/2015	3	2			1	3		1				
586	799474f	24	38.5	7/8/2015	3	2			1	3		1				
587	252604g	22	38.5	7/8/2015	3	2			2	3		1				
588	002470d	35	38.3	8/8/2015	3	2			1	3		1				
589	234870g	30	40.2	7/9/2014	1	1			1	3	2	2	1			
590	146755g	24	38.3	7/8/2015	3	1			1	2		1				
591	392402f	29	40	7/8/2015	2	2			1	3		2	4			
592	127765g	28	37.2	7/8/2015	3	2			1	4		1				
593	200303g	26	39.4	7/8/2015	1	1			1	3	2	2	1			
594	935196a	24	38.5	7/15/2015	1	1			1	2	1	2	2			
595	325882f	26	38.6	7/10/2015	3	2			1	3		1				
596	151897g	24	39.2	7/14/2015	2	1	1		1	3	3	2	3			
597	208412g	30	40.1	7/9/2015	1	2			1	3	2	2	1			
598	118131g	25	38.6	7/10/2015	1	1	1		1	3	1	2	1			
599	180095g	28	38.5	7/15/2015	3	2			1	3		1				
600	170479g	38	37.2	7/10/2015	2	2	2		1	3	3	2	4			
601	141154b	33	37.2	7/11/2015	3	2	2		1	3		1				
602	203839g	25	40.5	7/11/2015	1	2			1	2	2	2	1			
603	960385f	27	40	7/11/2015	1	1			1	3	2	2	1			
604	238848g	27	37.3	7/11/2015	1	2			2	3		3			1	
605	261052g	29	37.2	7/15/2015	3	2			1	3		3			1	
606		22														
607	142840g	21	39	7/12/2015	1	1			1	3	1	2	1			
608	326250f	21	37.3	7/13/2015	3	2			1	3		1				
609	416998d	28	37.1	7/11/2015	2	1	2	Hypo thyroid	1	4		3			3	
610	114473g	22		7/14/2015												
611	171730g	35	39	7/13/2015	1	2	2		1	4	2	2	1			
612	180107f	28	40.3	7/13/2015	1	1			1	3	2	2	1			
613	130980g	24	40.4	7/14/2015	1	1			1	2	2	2	1			
614	147380g	29	39.2	7/13/2015	1	1			1	2	1	2	1			
615	763989f	40	37.3	7/13/2015	1	2	2		1	3	1	2	1			
616	163320g	25	40.2	7/14/2015	1	1	2		1	3	2	2	1			
617	202423g	34	39	7/13/2015	1	1	1		1	2	2	2	1			
618	600721d	35	38	7/15/2015	3	2			1	2		1				
619	268979g	29	41.5	7/14/2015	1	1			1	3	1	2	1			
620	102054f	31	38.4	7/15/2015	3	2			2	3		1				
621	372107d	29	37.4	7/15/2015	1	2	1		2	3	1	2	4			
622	857609d	26	38.6	7/15/2015	3	2			1	3		1				
623	149075g	22	40.5	7/16/2015	1	1			1	3	1	2	1			
624		22														
625	133955g	28	38.3	7/15/2015	1	1			1	2	2	2	1			
626	025418g	24	39	7/16/2015	1	1			1	2	1	2	1			
627	967243f	28	38.3	7/21/2015	1	1	1		2	3	2	2	1			
628	245023g	20	38.3	7/16/2015	2	1			1	2	4	3			2	
629	964519f	27	41.1	7/17/2015	1	1			2	2	2	2	1			
630	979211d	34	38.1	7/16/2015	1	2	2		2	3	2	2	1			
631	176603g	21	39.3	7/16/2015	2	1			1	3	2	2	3			
632	149826g	24	39	7/16/2015	2	1			1	2		2	2			
633	130218g	26	39	7/21/2015	1	1	1		1	2	2	2	1			
634	964526f	26	39.2	7/17/2015	1	1			1	3		2	2			
635	531524d	31	39.4	7/21/2015	1	2	1		2	4	2	2	1			

electcs	dos	bld loss	Intra op	Bld trans	Hosp stay	Evi endo	Feb morbi	sursite	Ther anti	Indi ther	theraothe	allergic	R0 eadmis	Anti bio1	Hos visit	Rea read	Read oth	Hosp stay1
	1	1		2	4	2	2	2	2			2	2					
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	1	1		2	3	2	2	2	2			2	2					
1	1	1		2	4	2	2	2	2			2	2					
1	2	2	1	2	3	2	2	1	2			2	2					
1	1	1		2	5	2	2	2	2			2	2					
	1	1		2	3	2	2	2	2			2	2					
	1	1		2	3	2	2	2	2			2	2					
	1	1		2	3	2	2	2	2			2	2					
	1	1		2	3	2	2	2	2			2	2					
	1	1		2	3	2	2	1	2			2	1	2	2	4		1
	1	1		2	4	2	2	2	2			2	2					
	1	1		2	4	2	2	2	2			2	2					
	1	1		2	4	2	2	2	2			2	2					
	1	1		2	3	2	2	2	2			2	2					
	1	1		2	4	2	2	2	2			2	2	2	2			2
	1	1		2	7	1		2	1	2		2	2	2	1			
	1	1		2	4	2	2	2	2			2	2					
	1	1		2	3	2	2	2	2			2	2	2	1			
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	1	2	1	1	5	2	2	2	2			2	2					
	1	2			5	2	2	2	2			2	2					
	1	1		2	3	2	2	2	2			2	2					
2	1	2		2	6	2	2	2	2			2	2					
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	1	2	3	2	6	2		2	1	4		2	2					
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	1	1		2	4	2	2	2	2			2	2					
	1	1		2	4	2	2	1	2			2	2					
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	1	1		2	4	2	2	2	2			2	2					
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	1	1		2	4	2	2	2	2			2	2					
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2	1	1		2	4	2	2	2	2			2	2						
3	1	2		2	4	2	2	2	2			2	2						
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	1	2		2	5	1	2	2	1	2		1	2						
	1	1		2	4	2	2	2	2	2		2	2						
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	1	1		2	4	2	2	1	2	3		2	2						
	1	2		2	5	2	2	2	2			2	2						
	1	2	1	1	5	1			1	2		2	2						
1	1	1		2	4	2	2	2	2			2	2						
1	1	1		2	4	2	2	2	2			2	2						
	1	2	1	2	4	2	2	2	2			2	2						
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